

APPLICATION  
FOR  
UNITED STATES LETTERS PATENT  
TITLE OF INVENTION  
**METHOD AND DEVICE FOR SECURING BODY TISSUE**

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## CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation-in-part of U.S. Patent Application No. 10/228,855, filed August, 27 2002. This application is also a continuation-in-part of U.S. Patent Application No. 10/458,117, filed June 10, 2003, which is a divisional of U.S. Patent Application No. 10/076,919, filed February 15, 2002, now U.S. Patent No. 6,585,750, which is a divisional of U.S. Patent Application No. 09/524,397, filed March 13, 2000, now U.S. Patent No. 6,368,343. The contents of each of the above applications and patents are herein incorporated by reference.

## FIELD OF THE INVENTION

[0002] The present invention relates to methods and devices for securing body tissue by using ultrasonic vibratory energy and other forms of energy.

## BACKGROUND OF THE INVENTION

[0003] Difficulty has been encountered in securing sutures against movement relative to body tissue. A knot may be tied in a suture to prevent loosening of the suture. However, the knot weakens a portion of the suture and reduces the overall force transmitting capability of the suture. It has been suggested that a suture could be secured using a suture retainer in the manner disclosed in U.S. Patents Nos. 5,735,875 and 6,010,525.

[0004] When a suture retainer is used to maintain a suture in a desired position relative to body tissue, the material of the suture retainer may be pressed against the suture. During pressing of the material of the retainer against the suture, the suture may be heated to promote a flowing of the material of the suture retainer and bonding to the material of the suture retainer to the surface of the suture by heating material of the suture retainer into its transition temperature range.

[0005] When the material of the suture retainer is heated into its transition temperature range, the material changes from a solid condition in which it has a fixed form to a soft or

viscous condition. When the material of a suture retainer has been heated into the transition temperature range, the material can be molded around an outer side surface of a suture and bonded to the suture without significant deformation of the suture. The transition temperature ranges for various polymers which are suitable for forming suture retainers are disclosed in the aforementioned U.S. Patent No. 5,735,875.

## SUMMARY OF THE INVENTION

[0006] The present invention provides a new and improved method for use in securing body tissue. If desired, a suture retainer may be used to grip the suture. When a suture retainer is used, ultrasonic vibratory energy is transmitted to the material of the suture retainer to effect a heating of at least some of the material of the suture retainer. Portions of the suture retainer are then bonded to each other and/or to the suture.

[0007] It may be desired to retain layers of body tissue in linear apposition with each other. When this is to be done, a suture is used to hold the layers of body tissue in linear apposition after they have been approximated to each other. The suture may be secured relative to the body tissue by a suture retainer or crimp. Alternatively, sections of the suture may be secured together. To secure the suture relative to the body tissue, ultrasonic vibratory energy is applied to either the suture or the suture retainer. The ultrasonic energy may be applied while the suture is being tensioned with a predetermined force and while a predetermined force is being transmitted to the body tissue.

[0008] The suture retainer or crimp may have any one of many different constructions. One specific suture retainer constructed in accordance with one of the features of the present invention includes one or more passages through which one or more sections of the suture are inserted. In another embodiment of the invention, the suture retainer has sections which are formed separately from each other. The sections of the suture retainer are connected with the suture and/or each other by transmitting ultrasonic vibratory energy to at least one of the sections of the suture.

**[0009]** If desired, the suture may be wrapped around a portion of the suture retainer. The suture retainer may be provided with one or more recesses into which one or more sections of the suture are moved. The transmission of ultrasonic vibratory energy to the suture retainer is utilized to effect a bonding of portions of the suture retainer with each other and/or with the suture.

**[0010]** The suture retainer may be omitted and sections of the suture bonded to each other. When this is to be done, ultrasonic vibratory energy is transmitted to the sections of the suture. Force is applied against opposite sides of the sections of the suture to increase the extent of the sections of the suture in a direction transverse to the sections of the suture. As the transverse extent of the suture is increased, areas on outer side surfaces of the sections of the suture are increased.

## **BRIEF DESCRIPTION OF THE DRAWINGS**

**[0011]** The foregoing and other features of the invention will become more apparent upon a consideration of the following description taken in connection with the accompanying drawings wherein:

**[0012]** FIG. 1 is a schematic illustration depicting the manner in which layers of body tissue are moved into linear apposition with each other and secured with a suture and suture retainer;

**[0013]** FIG. 2 is a schematic fragmentary sectional view illustrating the manner in which the suture and suture retainer of FIG. 1 are positioned relative to each other;

**[0014]** FIG. 3 is a fragmentary schematic illustration depicting the manner in which ultrasonic vibratory energy is applied to the suture retainer of FIG. 2;

**[0015]** FIG. 4 is a schematic fragmentary sectional view of another embodiment of the invention and illustrating the approximation of layers of tissue by tensioning a suture with a

predetermined force and pressing a suture retainer against the body tissue with a predetermined force;

[0016] FIG. 5 is a schematic fragmentary sectional view of another embodiment of the invention and illustrating the manner in a vibration applicator member engages a suture retainer which is being pressed against body tissue with a predetermined force while an associated suture is tensioned with a predetermined force;

[0017] FIG. 6 is a schematic fragmentary pictorial illustration of another embodiment of the invention and depicting the construction of sections of a suture retainer and the relationship of the sections of the suture retainer to apparatus for applying ultrasonic vibratory energy to the suture retainer;

[0018] FIG. 7 is a schematic pictorial illustration of an embodiment of the invention in which a suture retainer has a pair of passages for receiving sections of a suture;

[0019] FIG. 8 is a schematic illustration depicting the manner in which ultrasonic vibratory energy is applied to the suture retainer of FIG. 7;

[0020] FIG. 9 is an exploded fragmentary schematic illustration of another embodiment of the invention and depicting the manner in which a suture is wrapped around a section of a suture retainer and the relationship of apparatus for applying ultrasonic vibratory energy to sections of the suture retainer;

[0021] FIG. 10 is a schematic pictorial illustration of another embodiment of the invention and depicting the manner in which sections of a suture extend through passages in a section of a suture retainer;

[0022] FIG. 11 is a schematic fragmentary sectional view depicting the relationship of the section of the suture retainer illustrated in FIG. 10 to other sections of the suture retainer and to an apparatus for applying ultrasonic vibratory energy to the suture retainer;

[0023] FIG. 12 is a schematic illustration of another embodiment of the invention and depicting the relationship between sections of a suture and sections of a suture retainer;

[0024] FIG. 13 is a top plan view, taken generally along the line 13-13 of FIG. 12, illustrating the relationship of the sections of the suture retainer and suture to an apparatus for applying ultrasonic vibratory energy to the suture retainer;

[0025] FIG. 14 is a schematic illustration of another embodiment of the invention and depicting the manner in which sections of a suture are wrapped around a section of a suture retainer;

[0026] FIG. 15 is a schematic sectional view, taken generally along the line 15-15 of FIG. 14, illustrating the relationship between sections of the suture retainer and an apparatus for applying ultrasonic vibratory energy to the suture retainer;

[0027] FIG. 16 is a schematic plan view of another embodiment of the invention, illustrating the relationship of sections of a suture to recesses formed in a suture retainer which is disposed between portions of an apparatus for applying ultrasonic vibratory energy to the suture retainer;

[0028] FIG. 17 is an enlarged fragmentary schematic illustration depicting the manner in which a section of the suture is moved into one of the recesses in the suture retainer of FIG. 16;

[0029] FIG. 18 is a schematic pictorial illustration depicting the manner in which another embodiment of the suture retainer is positioned relative to the suture;

[0030] FIG. 19 is a plan view, taken generally along the line 19-19 of FIG. 18, illustrating the relationship between the suture retainer and the suture;

[0031] FIG. 20 is a plan view, generally similar to FIG. 19, illustrating the relationship of an apparatus for applying ultrasonic vibratory energy to the suture retainer and the suture retainer and suture of FIG. 19;

**[0032]** FIG. 21 is a schematic pictorial illustration of an embodiment of the suture retainer having a recess which receives a portion of a suture;

**[0033]** FIG. 22 is a plan view of another embodiment of the invention and illustrating the manner in which a suture is positioned in a recess in the suture retainer and the relationship of apparatus for applying ultrasonic vibratory energy to the suture retainer;

**[0034]** FIG. 23 is a schematic illustration of another embodiment of the invention and depicting the manner in which a suture and a suture retainer are utilized to hold layers of body tissue in apposition with each other;

**[0035]** FIG. 24 is a schematic illustration of one apparatus for applying ultrasonic vibratory energy to a suture retainer;

**[0036]** FIG. 25 is a schematic illustration of a second apparatus for applying ultrasonic vibratory energy to a suture retainer;

**[0037]** FIG. 25A is a schematic illustration of an ultrasonic vibratory transmission device for FIGS. 24 and 25;

**[0038]** FIG. 26 is a schematic illustration, similar to FIG. 1, depicting the manner in which layers of body tissue are moved into linear apposition with each other and secured with a suture;

**[0039]** FIG. 27 is a schematic fragmentary sectional view illustrating the manner in which sections of the suture of FIG. 26 are positioned relative to each other and to apparatus which applies ultrasonic vibratory energy to the sections of the suture;

**[0040]** FIG. 28 is a schematic illustration depicting the manner in which sections of the suture of FIG. 27 are extended;

**[0041]** FIG. 29 is a schematic illustration of another embodiment of the suture retainer of FIGS. 1-4;

**[0042]** FIGS. 30A-30B are schematic illustrations of another embodiment of the invention and depicting the relationship between sections of a suture and sections of a suture retainer;

**[0043]** FIG. 31 is a schematic illustration of another embodiment of the invention and depicting the relationship between sections of a suture and sections of a suture retainer;

**[0044]** FIG. 32 is a schematic illustration of another embodiment of the invention and depicting the relationship between sections of a suture and sections of a suture retainer;

**[0045]** FIGS. 33A-33B are schematic illustrations of another embodiment of the invention and depicting the relationship between sections of a suture and sections of a suture retainer;

**[0046]** FIGS. 34A-34B are schematic illustrations of another embodiment of the invention and depicting the relationship between sections of a suture and the suture retainer;

**[0047]** FIGS. 35A-35B are schematic illustrations of another embodiment of the invention and depicting the relationship between sections of a suture and the suture retainer;

**[0048]** FIGS. 36A-36C are schematic illustrations of exemplary shaped horn configurations for use with the suture retainer of FIGS. 35;

**[0049]** FIGS. 37A-37B are schematic illustrations of another embodiment of the invention and depicting the relationship between sections of a suture and the suture retainer;

**[0050]** FIG. 38A-38B are schematic illustrations of another embodiment of the invention and depicting the relationship between sections of a suture and the suture retainer;

**[0051]** FIGS. 39A-39B are schematic illustrations of a tissue retainer of the present invention;

**[0052]** FIG. 40 is a fragmentary schematic illustration depicting the manner in which a suture and an suture retainer are positioned relative to body tissue;

- [0053] FIG. 41 is an enlarged schematic illustration of the retainer of FIG. 40;
- [0054] FIG. 42 is an exploded schematic pictorial illustration depicting the construction of a base section and cover section of the retainer of FIGS. 40 and 41;
- [0055] FIG. 43 is an exploded schematic pictorial illustration, further illustrating the construction of the base and cover sections of the retainer;
- [0056] FIG. 44 is an exploded schematic pictorial illustration, further illustrating the construction of the base and cover sections of the retainer;
- [0057] FIG. 45 is an exploded schematic pictorial illustration further illustrating the construction of the base and cover sections of the retainer;
- [0058] FIG. 46 is a schematic sectional view depicting the relationship between the base and cover sections of the retainer of FIGS. 40-45 with portions of the suture disposed in passages in the retainer; and
- [0059] FIG. 47 is a schematic fragmentary sectional view, generally similar to FIG. 46, depicting the manner in which end portions of projections on the cover section of the retainer are bonded to bottom portions of recesses in the base section of the retainer;
- [0060] FIG. 48 is a schematized sectional view of an embodiment of the apparatus of FIG. 25 for applying ultrasonic vibratory energy to a suture retainer;
- [0061] FIG. 49 is a schematic pictorial illustration of one embodiment of the applicator assembly of FIG. 48;
- [0062] FIG. 50 is an enlarged fragmentary schematic pictorial illustration of a portion of the applicator assembly of FIG. 49, illustrating a trigger and spring housing;
- [0063] FIG. 51 is an enlarged fragmentary schematic illustration of an end portion of the applicator assembly of FIG. 49;

[0064] FIG. 52 is a schematic illustration of a sleeve member for the apparatus of FIG. 48;

[0065] FIG. 53 is a schematic illustration of the sleeve member on the apparatus of FIG. 48;

[0066] FIG. 54 is a sectional view of the distal portion of the apparatus of FIG. 53 showing the sleeve member in a closed position; and

[0067] FIG. 55 is a sectional view of the distal portion of the apparatus of FIG. 53 showing the sleeve member in an open position.

## DETAILED DESCRIPTION OF THE INVENTION

### Embodiment of FIGS. 1-3

[0068] A tissue securing system 30 (FIG. 1) includes a suture 32 and a suture retainer or crimp 34. The suture 32 includes left and right sections 38 and 40 which are interconnected by a connector section 42. The suture retainer 34 grips the left and right sections 38 and 40 of the suture 32.

[0069] The tissue securing system 30 is used in a sterile, operating room environment to secure upper and lower layers 46 and 48 of soft, human body tissue in linear apposition with each other. Thus, the two layers 46 and 48 of human body tissue are approximated and held against movement relative to each other by the suture 32. Although the two layers 46 and 48 of body tissue have been schematically illustrated in FIG. 1 as being spaced apart from each other, they are held in a side-by-side relationship with each other and pressed together by tightening the tissue securing system 30. Pressing the two layers 46 and 48 together with the tissue securing system 30 promotes healing of the tissue.

[0070] Although the tissue securing system 30 has been illustrated in FIG. 1 as being used to hold layers of soft tissue in linear apposition with each other, it is contemplated that the tissue securing system may be used in many different locations in a patient's body to secure

tissue. For example, the tissue securing system 30 could be utilized to secure soft tissue, such as a ligament or tendon, against movement relative to a bone. Alternatively, the tissue securing system 30 could be utilized to interconnect portions of a flexible conduit, such as a blood vessel or intestine. It should be understood that the tissue securing system 30 may be used with either hard body tissue, or soft body tissue, or both hard and soft body tissue.

**[0071]** If desired, a force distribution member, such as a button, could be utilized between the connector section 42 of the suture 32 and the lower layer 48 of body tissue. The force distribution member would distribute force over a relative large area of the lower layer 48 of body tissue. Similarly, a force distribution member, such as a button, could be utilized between the upper layer 46 of soft tissue and the left and right sections 38 and 40 of the suture 32 and the suture retainer 34.

**[0072]** It is also contemplated that the suture 32 could extend through a suture anchor and/or be connected with body tissue in a manner similar to that disclosed in U.S. Patents Nos. 5,584,862; 5,549,631; and/or 5,527,343. Of course, the suture 32 could be connected with body tissue in a different manner if desired. For example, the connector section 42 could be eliminated. If this is done, the left section 38 of the suture 32 could be connected with one suture anchor and the right section 40 of the suture could be connected with a second suture anchor.

**[0073]** Although the sections 38 and 40 of the suture 32 could extend straight through the suture retainer 34, in the illustrated embodiment of the invention, the sections 38 and 40 of the suture 32 are wrapped around portions of the suture retainer 34. Thus, the left section 38 of the suture 32 is wrapped around a portion 52 (FIG. 2) of the suture retainer 34. Similarly, the right section 40 of the suture is wrapped around a portion 54 of the suture retainer 34.

**[0074]** In the illustrated embodiment of the invention, the left section 38 of the suture 32 is wrapped for more than a complete turn around the portion 52 of the suture retainer and the right section 40 of the suture is wrapped for more than a complete turn around the portion 54 of the suture retainer. However, if desired, wrapping of the sections 38 and 40 of the suture 32

around the suture retainer 34 could be omitted or each of the sections of the suture could be wrapped for less than one complete turn around a portion of the suture retainer.

[0075] When the sections 38 and 40 of the suture 32 are wrapped around the portions 52 and 54 of the suture retainer 34, a plurality of bends are formed in each of the sections of the suture. Thus, bends 58, 60, 62 and 64 are formed in the section 38 of the suture 32 as it is wrapped around the portion 52 of the suture retainer 34. Similarly, bends 66, 68, 70 and 72 are formed in the section 40 of the suture 32 as it is wrapped around the portion 54 of the suture retainer 34. Of course, a greater number of bends would be formed in each of the sections 38 and 40 of the suture 32 if they were wrapped a greater number of times around the suture retainer 34.

[0076] Although the suture retainer 34 could have many different constructions and configurations, in the illustrated embodiment of the invention, the suture retainer 34 is integrally formed as one piece and has a spherical configuration. A cylindrical central passage 76 extends axially through the suture retainer 34 between upper and lower (as viewed in FIG. 2) polar regions of the spherical suture retainer. The two sections 38 and 40 of the suture 32 extend through the passage 76. The suture retainer 34 is formed separately from the suture 32 and is initially disconnected from the suture.

[0077] In the illustrated embodiment of the invention, two lengths of the left suture section 38 and two lengths of the right suture section 40 extend through the passage 76 as a result of the wrapping of the sections of the suture around the portions 52 and 54 of the suture retainer 34. However, the two sections 38 and 40 of the suture 32 could extend straight through the passage 76 without being wrapped around the portions 52 and 54 of the suture retainer 34. If this was done, only a single length of the left section 38 of the suture 32 would be disposed in the passage 76 adjacent to a single length of the right section 40 of the suture 32. Of course, if the sections 38 and 40 of the suture 32 were wrapped around the portions 52 and 54 of the suture retainer for a greater number of turns, a greater number of lengths of the sections 38 and 40 of the suture 32 would extend through the passage 76.

**[0078]** In the illustrated embodiment of the suture retainer 34, a pair of grooves or recesses 80 and 82 extend radially inward from a spherical outer side surface 84 of the suture retainer 34. The grooves or recesses 80 and 82 are relatively deep so that the portions 52 and 54 of the suture retainer around which the suture is wrapped are relatively slender. This results in relatively short lengths of the sections 38 and 40 of the suture being disposed in engagement with the outer side surface of the suture retainer 34 adjacent to the upper and lower polar regions of the suture retainer.

**[0079]** In the embodiment of the invention illustrated in FIG. 2, the grooves or recesses 80 and 82 extend inward from the outer side surface 84 of the suture retainer 34. The depth of the grooves or recesses 80 and 82 varies along the vertical (as viewed in FIG. 2) length of the grooves. However, it is contemplated that the grooves 80 and 82 could be constructed so as to have a uniform depth throughout their length. If this was done, the grooves 80 and 82 would have an arcuate configuration with centers of curvature which are coincident with the center of curvature of the spherical outer side surface 84 of the suture retainer 34.

**[0080]** Rather than opening radially outward to the outer side surface 84 of the suture retainer 34, the grooves 80 and 82 could be undercut to enclose the portions of the suture 32 disposed in the grooves. It is contemplated that the grooves could have any one of the groove configurations disclosed in U.S. Patent No. 6,010,525. The disclosure from the aforementioned U.S. Patent No. 6,010,525 is incorporated herein in its entirety by this reference thereto. Alternatively, the grooves 80 and 82 could be formed as passages which extend through the suture retainer 34 parallel to and spaced apart from the central passage 76.

**[0081]** It is contemplated that the suture retainer 34 may be formed of many different materials. However, it is contemplated that it will be preferred to form the suture retainer 34 of a biodegradable polymer. One biodegradable polymer which may be utilized is polycaprolactone. Alternatively, the suture retainer 34 could be formed of polyethylene oxide terephthalate or polybutylene terephthalate. The suture retainer 34 could be formed as a polyhydroxyalkanoate if desired. It is also contemplated that other biodegradable or other bioerodible copolymers could be utilized if desired.

**[0082]** Although it is preferred to form the suture retainer 34 of a biodegradable material, the suture retainer could be formed of a material which is not biodegradable. For example, the suture retainer 34 could be formed of an acetyl resin, such as “Delrin” (trademark). Alternatively, the suture retainer 34 could be formed of a para-dimethylamino-benzenediazo sodium sulfonate, such as “Dexon” (trademark). If desired, the suture retainer 34 could be formed of nylon. Additionally, the suture retainer 34 may be made of a heat shrink material.

**[0083]** The suture 32 may be formed of the same material as the suture retainer 34 or of a different material. The suture 32 may be formed of natural or synthetic materials. The suture 32 may be a monofilament or may be formed of a plurality of interconnected filaments. The suture 32 may be biodegradable or non-biodegradable. It is contemplated that the suture retainer 34 could be utilized in association with force transmitting elements other than a suture. It is believed that it may be preferred to form the suture 32 of the same material as the suture retainer 34.

**[0084]** In accordance with a feature of the present invention, ultrasonic vibratory energy is utilized to cause the suture retainer 34 to grip the suture 32. The ultrasonic vibratory energy is at a frequency above that which can normally be detected by the human ear, that is, above 16 to 20 kilohertz. Although there are a wide range of frequencies which may be utilized, it is believed that it will be desirable to use ultrasonic energy having a frequency of between 20 kilohertz and 70 kilohertz. However, higher frequency vibratory energy could be utilized if desired.

**[0085]** The ultrasonic vibratory energy may be continuously applied, pulsed or modulated in various fashions. Any one of many known transducers may be utilized to change electrical energy into mechanical vibrations having an ultrasonic frequency. The transducers may be piezoelectric, ferroelectric, or magnetostrictive. One commercial source of apparatus which may be utilized to provide ultrasonic vibratory energy is Dukane Corporation, Ultrasonics Division, 2900 Dukane Drive, St. Charles, Illinois. Of course, there are other sources of apparatus which can be utilized to provide ultrasonic vibratory energy.

[0086] The ultrasonic vibratory energy creates frictional heat at the areas where the suture retainer 34 and suture 32 are disposed in engagement with each other. The frictional heat provided by the ultrasonic vibratory energy is effective to heat the material of the suture retainer 34 into its transition temperature range while the material of the suture 32 remains at a temperature close to or below its transition temperature range. For example, the suture 32 may be formed of a material having a transition temperature range which is above 190 degrees Celsius. The suture retainer 34 may have a transition temperature range which, for the most part, is at a temperature below 190 degrees Celsius.

[0087] However, it should be understood that at least a portion or even the entire transition temperature range for the suture 32 could be co-extensive with the transition range for the suture retainer 34. In fact, the transition temperature range of the suture 32 could extend below the transition temperature range of the suture retainer 34. However, it is believed that it may be preferred to have the transition temperature range for the suture 32 above at least a portion of the transition temperature range of the suture retainer 34.

[0088] Once the material of the suture retainer 34 has been heated into its transition temperature range by the ultrasonic vibratory energy, the plastic material of the suture retainer 34 loses its rigidity and becomes soft and viscous. The softened material of the suture retainer is moldable and flows, when subjected to pressure, around the suture 32 without significant deformation of the suture. However, the temperature range into which the suture 32 is heated and the pressure applied against the suture may result in some deformation of the suture.

[0089] Although it is contemplated that the suture 32 and suture retainer 34 could be made of many different materials, the suture and suture retainer may be formed of a plastic material which is a biopolymer. For example, the suture 32 and/or suture retainer 34 may be formed of polyglycolide which is commercial available under the trademark "Dexon". Polyglycolide is a crystalline material that melts at about 225° Celsius. However, the suture could be formed of a glycolide-based copolymer which is commercially available under the trademark "Vicryl".

**[0090]** The suture retainer 34 is also made of a plastic material which may be a biopolymer. For example, the suture retainer 34 may be made of polydellactide. The transition temperature of polydellactide will vary depending upon the specific characteristics of the material. However, a suture retainer 34 formed of polydellactide may have a transition temperature range of about 75° Celsius to about 120° Celsius. Other materials which may be utilized for forming the suture 32 and/or suture retainer 34 are disclosed in U.S. Patent No. 5,735,875. The disclosure in the aforementioned U.S. Patent No. 5,735,875 is hereby incorporated herein in its entirety by this reference thereto.

**[0091]** In order to promote a bonding of the material of the suture retainer 34 to the suture 32, both the suture and suture retainer may be formed of the same amorphous thermoplastic material. For example, both the suture 32 and suture retainer 34 may be formed of a polyhydroxy-alkanoate. Alternatively, both the suture 32 and suture retainer 34 may be formed of nylon. It is contemplated that the suture 32 and suture retainer 34 could be formed of different amorphous polymers which are similar, that is, have the same or similar chemical properties.

**[0092]** When the ultrasonic vibratory energy is to be applied to the suture retainer 34, a supportive member or anvil 90 (FIG. 3) is positioned in engagement with one side of the suture retainer 34. A horn or acoustic tool 92 is positioned in engagement with the opposite side of the suture retainer 34. Force, indicated schematically by arrows 96 and 98 in FIG. 3, is applied against the suture retainer 34 by the anvil 90 and horn 92.

**[0093]** The horn is vibrated, horizontally as viewed in FIG. 3, at a rate in excess of 20 kilohertz. Although the horn 92 may be vibrated at any desired frequency within range of 20 kilohertz to 70 kilohertz, it is believed that it may be desirable to vibrate the horn 92 at a rate which is close to or greater than 70 kilohertz. The horn 92 is vibrated for a dwell time which is sufficient to transmit enough ultrasonic vibratory energy to the suture retainer 34 to heat at least a portion of the material of the suture retainer 34 into its transition temperature range.

**[0094]** To effect a heating of the material of the suture retainer 34, mechanical vibrations are transmitted from the horn 92 through the material of the retainer 34 to a location adjacent to

an interface between the suture 32 and the suture retainer 34. The frictional heat created by the ultrasonic vibratory energy transmitted to the suture retainer from the horn 92 is sufficient to heat the material of the suture retainer 34 at locations adjacent to the suture 32, into the transition temperature range of the material of the suture retainer. As this occurs, the passage 76 and grooves 80 and 82 collapse under the influence of the force indicated at 96 and 98 in FIG. 3 and the ultrasonic vibratory energy transmitted from the horn 92.

[0095] The vibration of the horn 92 is then interrupted and the material of the suture retainer 34 begins to cool. The clamping force, indicated by the arrows 96 and 98, is maintained against opposite sides of the suture retainer 34 by the anvil 90 and horn 92 during the time which ultrasonic vibratory energy is transmitted from the horn 92 to the material of the suture retainer 34. After interruption of the transmission of ultrasonic vibratory energy, the clamping force, indicated schematically by the arrows 96 and 98 and applied by the anvil 90 and horn 92, is maintained for a predetermined amount of time sufficient to allow the material of the suture retainer to cool and bond to both itself and the suture 32.

[0096] If desired, the force, indicated schematically by the arrows 96 and 98 in FIG. 3, applied by the anvil 90 and horn 92 to the suture retainer 34 may be increased as the transmission of ultrasonic vibratory energy to the suture retainer 34 from the horn 92 is interrupted. The force, indicated schematically by the arrows 96 and 98 in FIG. 3, is sufficient to cause the passage 76 and recesses 80 and 82 to collapse as the suture retainer 34 is heated by ultrasonic vibratory energy and subsequently allowed to cool.

[0097] The length of time for which ultrasonic vibratory energy is transmitted to the suture retainer 34 may vary as a function of the amplitude and frequency of the ultrasonic vibratory energy transmitted to the suture retainer. It is contemplated that the frequency of the ultrasonic vibratory energy will be in a range of between 20 kilohertz and 70 kilohertz. It is contemplated that the amplitude of the ultrasonic vibrations may vary within a range of 0.0008 inches to 0.0050 inches depending upon the design of the suture retainer 34 and the material forming the suture retainer.

**[0098]** It is also contemplated that the force, indicated schematically by the arrows 96 and 98, applied against the suture retainer 34 may vary depending upon the construction of the suture retainer 34 and the material forming the suture retainer. For example, a force of approximately 1-20 pounds may be applied against the suture retainer 34 by both the anvil 90 and horn 92. The amount of force applied is a function of a number of factors, including, the material of the retainer and suture, the size of the retainer and suture, the frequency of the ultrasonic vibratory energy and the duration of application of the ultrasonic vibratory energy.

**[0099]** It is believed that the ultrasonic vibratory energy may be transmitted from the horn 92 to the suture retainer 34 for a period of time which varies between 0.25 seconds and 1.0 second. After the transmission of ultrasonic vibratory energy has been interrupted, the force, indicated by the arrows 96 and 98, may continue to be applied to the suture retainer 34 by the anvil 90 and horn 92 for approximately 1.0 seconds.

**[0100]** The extent to which the suture retainer 34 is compressed by the force 96 and 98 applied against the suture retainer by the anvil 90 and horn 92 has been illustrated schematically in FIG. 3. It is contemplated that the distance through which the anvil 90 and horn 92 move toward each other to compress the suture retainer 34 may be from 0.010 inches to 0.050 inches. Of course, the distance through which the suture retainer 34 is compressed by the anvil 90 and horn 92 may be different for suture retainers having different constructions and/or formed of different materials.

**[0101]** It should be understood that the foregoing specific operating characteristics, for example, amplitude and frequency of the ultrasonic vibratory energy transmitted from the horn 92 to the suture retainer 34, force applied against the suture retainer by the anvil 90 and horn 92, time for which force and/or ultrasonic vibratory energy is applied, and the distance through which the suture retainer is compressed, have been set forth herein for purposes of clarity of description. It is contemplated that the foregoing specific numerical values will be different for different embodiments of the invention and may vary extensively from the exemplary values set forth.

**[0102]** When the two layers 46 and 48 of body tissue are to be held in position relative to each other by the tissue securing system 30, the suture 32 is positioned relative to the layers of body tissue. The left and right sections 38 and 40 of the suture 32 extend through the two layers 46 and 48 of tissue. Although the sections 38 and 40 of the suture 32 have been illustrated schematically in FIG. 1 as extending through passages in the layers 46 and 48 of body tissue, the passages could be omitted and the suture 32 sewn through the body tissue without forming passages in the body tissue.

**[0103]** In the embodiment of the invention illustrated in FIG. 1, the sections 38 and 40 of the suture 32 are interconnected by the connector section 42 which extends along one side of the layer 48 of body tissue. If desired, the sections 38 and 40 of the suture 32 could be connected with a single anchor embedded in either hard or soft body tissue. Alternatively, a separate anchor could be provided for each of the sections 38 and 40 of the suture 32. These anchors could be embedded in the body tissue or disposed adjacent to one side of the body tissue.

**[0104]** When the suture 32 has been positioned relative to the two layers 46 and 48 of body tissue, the two layers of body tissue are pressed against each other in linear apposition. The suture retainer 34 is then connected with the suture 32. When the suture retainer 34 is to be connected with the suture 32, the left (as viewed in FIG. 2) section 38 of the suture is inserted through the central passage 76 in the suture retainer 34. The left section 38 of the suture 32 is then wrapped around the portion 52 of the suture retainer 34 and again inserted through the central passage 76.

**[0105]** Similarly, the right section 40 of the suture 32 is inserted through the central passage 76 and wrapped around the portion 54 of the suture retainer 34. The right section 40 of the suture is then inserted through the central passage 76 for a second time. This results in the suture 32 being connected with the suture retainer 34 in the manner illustrated schematically in FIG. 2.

**[0106]** The suture retainer 34 is then moved downward (as viewed in FIGS. 1 and 2) along the suture 32 toward the upper layer 46 of body tissue. The suture 32 is tensioned with a

predetermined force during downward movement of the suture retainer 34 toward the body tissue. As the suture retainer 34 moves downward (as viewed in FIGS. 1 and 2) along the suture 32 toward the upper layer 46 of body tissue, the turns formed in the sections of the suture around the portions 52 and 54 of the suture retainer 34 move downward toward the body tissue. Thus, the bends 58-64 in the section 38 of the suture 32 and the bends 66-72 in the section 40 of the suture 32 move along the suture toward the upper layer 46 of body tissue with the suture retainer 34.

**[0107]** As the suture retainer 34 is moved along the suture 32 toward the upper layer 46 of body tissue, a predetermined tension, indicated by arrows 102 and 104 in FIG. 3, is maintained in the sections 38 and 40 of the suture 32. The magnitude of the tension forces 102 and 104 in the sections 38 and 40 of the suture 32 is selected as a function of the characteristics of the layers 46 and 48 of body tissue and as a function of the strength of the suture.

**[0108]** As the suture retainer 34 moves downward (as viewed in FIGS. 1-3), the leading portion of the suture retainer moves into engagement with the upper layer 46 of body tissue (FIG. 3). The suture retainer 34 is then pressed against the upper layer 46 of body tissue. If desired, a force distribution member, such as a button, could be provided between the suture retainer 34 and the body tissue 46.

**[0109]** The suture retainer 34 is pressed downward against the body tissue 46 with a predetermined force, indicated schematically by an arrow 106 in FIG. 3, while a predetermined tension, indicated schematically by the arrows 102 and 104, is maintained in the suture 32. The force transmitted from the suture 32 and suture retainer 34 to the layers 46 and 48 of body tissue presses them together and, to some extent, compresses the layers of body tissue. This results in the layers of body tissue being held in linear apposition and being compressed to promote healing of the layers 46 and 48 of body tissue.

**[0110]** The force, indicated by the arrows 102 and 104, with which the sections 38 and 40 of the suture 32 are tensioned, may vary depending upon the material from which the suture is constructed and the size of the suture. By consulting a chart, a surgeon can select a suture size

and strength suitable for a particular use. Thus, a relatively large suture having substantial strength may be selected when body tissue is to be connected with a bone or when portions of a bone are to be interconnected by the suture. On the other hand, a relatively small suture size having a relatively small strength may be selected when delicate body tissue, such as stomach or intestinal tissue, is to be interconnected with the suture. The tension forces 102 and 104 in the sections 38 and 40 are determined as a function of the strength 32 of the suture and the characteristics of the body tissue through which the suture extends

**[0111]** The suture 34 is pressed against the body tissue with a force which is also a function of the size and strength of the suture 32 and the characteristics of the body tissue 46 and 48. One way in which force with which the suture 32 is tensioned and with which the suture 34 is pressed against body tissue is disclosed in U.S. Patent No. 6,159,234 filed July 7, 1999 by Peter M. Bonutti et al. and entitled "Method and Apparatus for Securing a Suture". The disclosure in the aforementioned '234 Patent is hereby incorporated herein by this reference thereto.

**[0112]** After the suture retainer 34 has been pressed against the body tissue with a predetermined force and the suture 32 tensioned with a predetermined force to compress the layers 46 and 48 of body tissue, ultrasonic vibratory energy is applied to the suture retainer. To apply the ultrasonic vibratory energy to the suture retainer 34, the anvil 90 (FIG. 3) is positioned in engagement with one side of the suture retainer and the horn 92 is positioned in engagement with the opposite side of the suture retainer. The anvil 90 and horn 92 are urged toward each other with a predetermined force, indicated schematically by the arrows 96 and 98 in FIG. 3.

**[0113]** The specific magnitude of the force 96 and 98 will vary depending upon the composition of the suture retainer 34 and the construction of the suture retainer. In addition, the magnitude of the force 96 and 98 will vary as a function of the desired extent of deformation of the suture retainer 34. When the suture retainer 34 has been heat softened by ultrasonic vibratory energy, the material of the suture retainer is pliable and is plastically deformed by the force applied against the suture retainer by the anvil 90 and horn 92.

**[0114]** In addition to the anvil 90 and horn 92, the apparatus for transmitting ultrasonic vibratory energy to the suture retainer 34 includes a generator (not shown) which changes standard electrical power into electrical energy at the desired ultrasonic frequency. A transducer (not shown) changes the electrical energy into low amplitude mechanical motion or vibration. These vibrations are transmitted to a booster which is used to increase or decrease the amplitude of the vibrations. The vibrations are then transmitted to the horn 92.

**[0115]** The ultrasonic vibratory energy transmitted to the suture retainer 34 from the horn 92 is converted into heat energy. When this occurs, the temperature of the material forming the suture retainer 34 increases. The heat tends to concentrate at a boundary between the suture 32 and the suture retainer 34. Thus, the heat tends to concentrate in the areas where the suture 32 engages the grooves 80 and 82 and the passage 76 (FIG. 2).

**[0116]** As the temperature of the suture retainer 34 increases, the material of the suture retainer is heated into the transition temperature range and softens. However, the material of the suture retainer 34 does not melt and become liquid. As the material of the suture retainer 34 softens, the forces 96 and 98 (FIG. 3) applied against the suture retainer cause the material of the suture retainer to flow or ooze around and engage the suture 32.

**[0117]** As the ultrasonic vibratory energy is effective to heat soften the material of the suture retainer 34, the grooves 80 and 82 close, that is, collapse. As the grooves 80 and 82 close, the central passage 76 also closes. As the grooves 80 and 82 and central passage 76 close, the softened material of the suture retainer 34 moves into engagement with the suture (FIG. 3).

**[0118]** The viscous material of the suture retainer 34 engages the suture 32 and bonds to the suture without significant deformation of the suture. The materials of the suture 32 and suture retainer 34 should be chemically compatible so that a molecular bond can be established between the suture retainer and the suture. Like materials, that is materials having chemical properties which are the same or very similar will usually bond together. However, dissimilar materials may bond if their melt temperatures are reasonably close and they are of like molecular structure. Generally speaking, amorphous polymers are readily bonded to each other.

**[0119]** The suture retainer 34 is formed separately from the suture 32. As the material of the suture retainer 34 bonds to the suture 32, the suture retainer 34 becomes fixedly connected to the suture.

**[0120]** If desired, heat may be transmitted directly to the suture retainer 34 during the transmission of ultrasonic vibratory energy to the suture retainer. The heat may be transmitted from a heating element disposed in the anvil 90 and/or the horn 92. Alternatively, a separate member could be utilized to transmit heat to the suture retainer 34.

**[0121]** In the embodiment of the invention illustrated in FIGS. 1-3, the anvil 90 and horn 92 have a configuration which corresponds to the arcuate configuration of the spherical outer side surface 84 (FIG. 2) of the suture retainer 34. The anvil 90 and horn 92 are configured so as to engage the material of the suture retainer 34 and to be spaced from the suture 32. This is to prevent excessive heating of the material of the suture 32 by the direct application of ultrasonic vibratory energy to the suture.

#### **Embodiment of FIG. 4**

**[0122]** In the embodiment of the invention illustrated in FIGS. 1-3, sections 38 and 40 of the suture 32 are wrapped around portions 52 and 54 of the suture retainer 34. In the embodiment of the invention illustrated in FIG. 4, a single section of the suture extends straight through a passage in the suture retainer. Since the embodiment of the invention illustrated in FIG. 4 is generally similar to the embodiment of the invention illustrated in FIGS. 1-3, similar terminology will be utilized to designate similar components. It should be understood that one or more of the features of any of the various embodiments of the invention disclosed herein may be used with the embodiment of the invention illustrated in FIG. 4.

**[0123]** In the embodiment of the invention illustrated in FIG. 4, a suture 112 is inserted through upper and lower (as viewed in FIG. 4) layers 114 and 116 of human body tissue in a sterile operating room environment. A first or inner end portion 118 of the suture 112 is connected with a suture anchor 120. The suture anchor 120 could have any desired construction,

including the construction disclosed in U.S. Patents Nos. 5,584,862; 5,549,631; and/or 5,527,343. However, the illustrated embodiment of the suture anchor 120 is a circular disc or button having a pair of central openings around which the end portion 118 of the suture 112 is tied.

**[0124]** The suture 112 extends straight through the lower layer 116 and upper layer 114 of body tissue. The two layers of body tissue are disposed in linear apposition with each other and are compressed between the suture anchor 120 and a suture retainer 124. The upper and lower layers 114 and 116 of body tissue are compressed by force applied against the body tissue by the suture retainer 124 and suture anchor 120. By having the layers 114 and 116 of body tissue approximated with each other and by pressing the layers of tissue together, healing of the tissue is promoted.

**[0125]** Although the layers 114 and 116 are layers of soft body tissue, the suture 112, suture anchor 120, and suture retainer 124 could be used with hard body tissue in the manner disclosed in U.S. Patent No. 5,921,986. Alternatively, the suture 112, suture anchor 120, and suture retainer 124 could be used to connect soft body tissue with hard body tissue.

**[0126]** The suture retainer 124 has a spherical configuration and is formed separately from the suture 112. A cylindrical passage 126 extends axially through the suture retainer 124. Although the suture 112 extends straight through the passage 126 in the suture retainer 124, bends and/or loops could be formed in the suture 112 around the suture retainer 124.

**[0127]** The suture retainer 124 is formed of one piece of spherical polymeric material having a relatively low coefficient of friction. The suture retainer 124 may be formed of many different materials. However, it is believed that it may be preferred to form the suture retainer 124 of a biodegradable polymer such as polycaprolactone or polyhydroxyalkanoate. It is contemplated that other biodegradable or bioerodible polymers could be utilized if desired. It is believed that it may be preferred to form the suture retainer 124 of an amorphous thermoplastic material.

**[0128]** The suture 112 may be a monofilament or may be formed of a plurality of interconnected filaments. The suture 112 may be biodegradable or non-biodegradable. It is believed that it will be preferred to form the suture 112 of the same material as the suture retainer 124. However, the suture 112 could be formed of a material which is different than the material of the suture retainer. The suture 112 may be formed of an amorphous thermoplastic having chemical properties which are the same or similar to the chemical properties of the suture retainer 124. For example, both the suture retainer 124 and the suture 112 may be formed of the same biodegradable polymer, such as polycaprolactone or polyhydroxyalkanoate.

**[0129]** The suture 112 is tensioned with a force which is a function of the size and strength of the suture. In addition, the suture retainer 124 is pressed against the upper layer 114 of body tissue with a force which is a function of the size and strength of the suture 112. Although the suture retainer 124 is disposed in direct engagement with and is pressed against an outer side surface of the upper layer 114 of body tissue, a force distribution member or button could be positioned between the suture retainer and the upper layer 114 of body tissue.

**[0130]** The suture 112 is tensioned by a force application assembly 130 which is connected with a second or outer end portion 132 of the suture 112. The force application assembly 130 includes a transducer or load cell 134 which provides an output signal indicative of a force, indicated schematically at 136 in FIG. 4, which is applied to the second or outer end portion 132 of the suture 112. The force 136 has a magnitude which is a function of the size and strength of the suture 112 and the characteristics of the body tissue with which the suture is associated, that is, the upper layer 114 and lower layer 116 of body tissue.

**[0131]** The suture retainer 124 is pressed against the body tissue with a force which is also a function of the strength and size of the suture 112. A force application member 140 is used to apply force against the suture retainer 124. The force application member 140 has a cylindrical opening 142 which extends through the force application member.

**[0132]** The suture 112 extends through the opening 142 in the force application member 140. A slot may be formed in the force application member 140 to enable the suture to be moved

into the opening 142. Alternatively, the suture 112 could be inserted through the opening 142 before the end portion of the suture is connected with the force application assembly 130.

**[0133]** Forces, indicated schematically at 146 and 148 in FIG. 4, are applied against opposite end portions 150 and 152 of the force application member 140 to press the suture retainer 124 against the upper layer 114 of body tissue or against a force transmitting member disposed between the suture retainer 124 and the upper layer 114 of body tissue. The combined force indicated schematically by the arrows 146 and 148 in FIG. 4, is a function of the size and strength of the suture 112 and the characteristics of the layers 114 and 116 of body tissue. It is contemplated that the combined forces 146 and 148 may be equal to the force 136. Alternatively, the summation of the forces 146 and 148 could exceed the force 136 or be less than the force 136.

**[0134]** The suture retainer 124 slides downward (as viewed in FIG. 4) along the suture 112 under the influence of the force application member 140. At this time, the suture 112 is tensioned by the force application assembly 130 so that the portion of the suture extending between the suture anchor 120 and the force application assembly 130 is straight, as illustrated in FIG. 4. However, at this time, the force which is applied to the outer end portion 132 by the force transmitting assembly may be substantially less than the force which is indicated schematically by the arrow 136 in FIG. 4.

**[0135]** After the suture retainer 124 has been moved along the suture 112 to the position illustrated in FIG. 4, the force applied against the suture retainer by the force application member 140 is increased. At the same time, the force applied to the outer end portion 132 of the suture 112 by the force application assembly 130 is increased. The force applied against the suture retainer by the force application member 140 is increased until the force, indicated schematically by the arrows 146 and 148 in FIG. 4, is equal to a predetermined force which is a function of the strength of the suture 112 and the characteristics of the layers 114 and 116 of body tissue. At the same time, the force applied to the outer end portion 132 of the suture 112 by the force application assembly 130 is increased to the force indicated schematically by the arrow 136 in FIG. 4. As was previously mentioned, the force indicated by the arrow 136 is a predetermined

function of the strength of the suture 112 and the characteristics of the layers 114 and 116 of body tissue.

[0136] While the suture 112 is being pulled straight under the influence of tension in the suture due to the force 136 and while the suture retainer 124 is being pressed against the upper layer 114 of body tissue or against a suitable force distribution member, the suture retainer 124 is heated to grip the suture 112. In accordance with one of the features of the invention, the suture retainer 124 is heated by the application of ultrasonic vibratory energy to the suture retainer. The ultrasonic vibratory energy is converted into heat by the molecules of the suture retainer 124. Thus, the mechanical ultrasonic vibrations applied against the suture retainer 124 cause molecular vibration of the material of the suture retainer and a heating of the suture retainer.

[0137] When a portion of the material forming the suture retainer 124 has been heated into its transition temperature range, the application of ultrasonic vibratory energy to the suture retainer 124 is interrupted. Heating the material forming the suture retainer 124 causes the material to lose its rigidity and soften. The material of the suture retainer 124 is not melted and does not become liquid by being heated into its transition temperature range. The softened material of the suture retainer 124 bonds to the suture 112 without significant deformation of the suture.

[0138] To apply ultrasonic vibratory energy to the suture retainer 124, a support member or anvil 160 engages one side, that is the left side as viewed in FIG. 4, of the suture retainer 124. At the same time, a horn or acoustic tool is pressed against the opposite or right side (as viewed in FIG. 4) of the suture retainer 124.

[0139] The anvil 160 and horn 162 are pressed against opposite sides of the suture retainer 124 with predetermined forces, indicated schematically by arrows 164 and 166 in FIG. 4. After the suture retainer 124 has been firmly clamped between the anvil 160 and horn 162, the horn is vibrated with an ultrasonic frequency, that is with a frequency which is greater than 20 kilohertz. It is contemplated that the horn 162 may be vibrated at a selected frequency within a range of ultrasonic frequencies which extends between 20 kilohertz and 70 kilohertz. Although

the particular ultrasonic frequency with which the horn 162 is vibrated will vary depending upon the composition and construction of the suture retainer 124, it is believed that it may be preferred to vibrate the horn 162 with a frequency which is close to or greater than 70 kilohertz.

**[0140]** The mechanical vibrations applied to the suture retainer 124 by the horn 162 are effective to heat a portion of the material of the suture retainer 124 into the transition temperature range. The heat tends to concentrate on the portion of the suture retainer 124 adjacent to the passage 126 and the suture 112. When the material of the suture retainer 124 adjacent to the suture 112 has been heated into its transition temperature range, the application of ultrasonic vibratory energy to the suture retainer 124 is interrupted. The forces 164 and 166 are effective to close or collapse the passage 126 and to press the softened material of the suture retainer 124 against the suture 112.

**[0141]** Although the application of ultrasonic vibratory energy to the suture retainer 124 is interrupted, the anvil 160 and horn 162 continue to apply the forces 164 and 166 against the softened material of the suture retainer. If desired, the forces 164 and 166 may be increased when the application of ultrasonic vibratory energy to the suture retainer 124 by the horn 162 is interrupted. The forces 164 and 166 firmly press the heat-softened material of the suture retainer 124 into the passage 126 to collapse the passage. The heat softened material of the suture retainer 124 is plastically deformed and pressed against the suture 112 by the forces 164 and 166 applied against the suture retainer by the anvil 160 and horn 162.

**[0142]** The forces 164 and 166 are maintained for a sufficient period of time to enable the material of the suture retainer 124 flow about the suture 112, securing the suture 112, without significant deformation of the suture. Once this has been achieved, application of the forces 164 and 166 is interrupted and the anvil 160 and horn 162 are withdrawn. The force application member 140 may then be disengaged from the suture retainer and the force application assembly 130 disconnected from the outer end portion 132 of the suture 112.

**[0143]** When the layers 114 and 116 of body tissue are to be interconnected with the suture 112, suture anchor 120 and suture retainer 124, the upper layer 114 is moved into

apposition with the lower layer 116 of body tissue. The suture 112 is then connected with the suture anchor 120 and is inserted through the layers 114 and 116 of body tissue with a suitable needle. The outer end portion 132 of the suture 112 is then inserted through the passage 126.

**[0144]** The suture retainer 124 is then moved along the suture 112 into engagement with the upper layer 114 of body tissue. The force application member 140 is utilized to transmit the forces 146 and 148 to the suture retainer 124 to press the suture retainer against the upper layer 114 of body tissue. This results in the two layers 114 and 116 of body tissue being pressed firmly together between the suture retainer 124 and suture anchor 112. The forces 146 and 148 are transmitted to the suture retainer 124 through the force application member 140. The suture 112 is tensioned with a force 136 by the force application assembly 130.

**[0145]** The anvil 160 and horn 162 then compress the suture retainer 124 under the influence of the forces 164 and 166. Ultrasonic vibratory energy is transmitted to the suture retainer. Upon heating and softening of at least a portion of the material of the suture retainer 124, the transmission of ultrasonic energy to the suture retainer is interrupted and a securing of the suture 112 by the suture retainer occurs. After the suture retainer 124 has firmly gripped the suture 112, the application of the forces 164 and 166 is interrupted.

**[0146]** In the foregoing explanation of the manner in which the layers 114 and 116 of body tissue are secured by the use of the suture 112, suture anchor 120 and suture retainer 124, the suture retainer has been heated by only the application of ultrasonic vibratory energy to the suture retainer. However, it is contemplated that heat energy could be transmitted directly to the suture retainer along with the ultrasonic vibratory energy. If this was to be done, a heating element could be provided in the anvil 160 and/or horn 162. If desired, a separate heating element could engage the suture retainer to transmit the heat to the suture retainer separately from the anvil 160 and horn 162.

**[0147]** It is believed that it probably will be preferred to have the anvil 160 and horn 162 engage the suture retainer 124 at locations spaced from the suture 112 to prevent excessive

heating of the material of the suture. If desired, protective collars could be provided around the suture 112 at opposite ends of the passage 126.

#### **Embodiment of FIG. 5**

**[0148]** In the embodiment of the invention illustrated in FIG. 4, a single section of the suture 112 extends through a single passage 126 in the suture retainer 124. In addition, in the embodiment of the invention illustrated in FIG. 4, ultrasonic vibratory energy is applied to the suture retainer 124 by the horn 162 which also applies a compressive force 166 against the suture retainer. In the embodiment of the invention illustrated in FIG. 5, a plurality of sections of the suture extend through a plurality of passages in the suture retainer. In addition, ultrasonic vibratory energy is applied to the suture retainer by a member which is separate from the members which apply force against opposite sides of the suture retainer. Since the suture retainer of the embodiments of the invention illustrated in FIGS. 1-4 are similar to the embodiment of the suture retainer illustrated in FIG. 5, similar terminology will be utilized to designate similar components. It should be understood that one or more of the features of any of the embodiments of the invention disclosed herein may be used with the embodiment of the invention illustrated in FIG. 5.

**[0149]** A tissue securing system 174 is used in a sterile, operating room environment and includes a suture 176 and a suture retainer 178. The suture 176 has left and right sections 182 and 184 which extend into human body tissue 186. The body tissue 186 may include a plurality of layers which are approximated in linear apposition with each other in the manner previously described in conjunction with the embodiment of the invention illustrated in FIG. 1.

**[0150]** Although the suture 176 has been illustrated in FIG. 5 in association with soft body tissue 186, it is contemplated that the suture 176 could be associated with hard or hard and soft body tissue. In the embodiment of the invention illustrated in FIG. 5, the suture sections 182 and 184 are interconnected by a connector section which engages the body tissue in the manner illustrated schematically in FIG. 1. However, it should also be understood that the suture 176 could be associated with a suture anchor, similar to the suture anchor 120 of FIG. 4, if desired.

Rather than being disposed in engagement with an outer side surface of a layer of body tissue, the suture anchor could be embedded in the body tissue.

[0151] The suture retainer 178 has a spherical configuration and is formed separately from the suture 176. A pair of parallel passages 190 and 192 extend through the suture retainer 178 at locations offset to opposite sides of a central or polar axis of the suture retainer. A force transmitting member 194 is provided between the suture retainer 178 and the body tissue 186.

[0152] The sections 182 and 184 of the suture 176 press against opposite sides of the force transmitting member 194. If desired, the force transmitting member 194 could be provided with grooves or passages to receive the sections 182 and 184 of the suture 176. The force transmitting member 194 could be integrally formed as one piece with the suture retainer 178. Both the force transmitting member 194 and suture retainer 178 are formed separately from the suture 176.

[0153] In accordance with a feature of this embodiment of the invention, ultrasonic vibratory energy is applied to the suture retainer 178 by a horn or acoustic tool 200. The horn 200 extends into a cylindrical passage 202 formed in the suture retainer 178. The passage 202 extends parallel to and is disposed midway between the passages 190 and 192 which receive the sections 182 and 184 of the suture 176.

[0154] In the embodiment of the invention illustrated in FIG. 5, the horn 200 has a generally cylindrical configuration which corresponds to the cylindrical configuration of the passage 202. However, the horn 200 and passage 202 could have different configurations if desired. For example, the horn 200 and passage 202 could have frustroconical configurations.

[0155] A pair of force application members or anvils 206 and 208 are pressed against opposite sides of the suture retainer 178 with predetermined forces, indicated schematically by arrows 210 and 212 in FIG. 5. The anvils 206 and 208 have arcuate configurations which correspond to the arcuate configuration of the suture retainer 178. Of course, the anvils 206 and 208 could have a different configuration if desired.

[0156] When the tissue securing system 174 is to be utilized to secure the body tissue 186, the suture 176 is positioned relative to the body tissue in the manner illustrated schematically in FIG. 1. However, if desired, a separate anchor, similar to the anchor 120 of FIG. 4, could be connected with an end portion of each of the sections 182 and 184 of the suture 176. If this was done, the sections 182 and 184 of the suture 176 could be separate from each other and interconnected by the body tissue 176 and suture retainer 178. Thus, two separate segments of suture, that is the sections 182 and 184, would be interconnected by a single suture retainer.

[0157] After the suture 176 has been positioned relative to the body tissue, the upper (as viewed in FIG. 5) end portions of the sections 182 and 184 of the suture 176 are inserted through the passages 190 and 192. The force distribution member 194 is positioned between the suture retainer 178 and the body tissue 176. The sections 182 and 184 of the suture are then tensioned with a predetermined force. The suture retainer 178 is moved along the sections 182 and 184 of the suture 176 into engagement with the force distribution member 194.

[0158] When the suture retainer 178 has been moved along the sections 182 and 184 of the suture 176 into engagement with the force distribution member 194, a predetermined force is applied against suture retainer 178, in the manner similar to that indicated schematically in FIG. 4, to press the force transmitting member 194 against the body tissue 186 with a predetermined force. At the same time, the sections 182 and 184 of the suture 176 are tensioned with a predetermined force. If the sections 182 and 184 are formed by a single piece of suture 176, in the manner illustrated schematically in FIG. 1, a connector section of the suture is pulled against the body tissue to compress the body tissue between the suture retainer 178 and the connector section of the suture. Alternatively, if separate suture anchors are connected with the sections 182 and 184 of the suture 176, the two spaced apart suture anchors are pulled against the body tissue to compress the body tissue 186 between the suture anchors and the suture retainer 178.

[0159] While the suture 176 is being tensioned with a predetermined force and while the suture retainer 178 is being pressed against the force distribution member 194 with a predetermined force, the suture retainer 178 is deformed to grip the sections 182 and 184 of the

suture 176. This deformation of the suture retainer 178 results in a firm gripping of the sections 182 and 184 of the suture 176 to maintain a desired tension force in the suture and to maintain a desired compression force against the body tissue 186.

**[0160]** To deform the suture retainer 178 to grip the suture 176, the anvils 206 and 208 are pressed against opposite sides of the suture retainer with a predetermined force, as indicated schematically by the arrows 210 and 210 in FIG. 5. The horn 200 is then vibrated with an ultrasonic frequency to transmit ultrasonic vibratory energy to the suture retainer 178. It is contemplated that the horn 200 may be vibrated at a frequency of between 20 and 70 kilohertz. It is believed that it may be preferred to vibrate the horn 200 at a frequency which is close to or greater than 70 kilohertz.

**[0161]** Vibration of the horn 200 at ultrasonic frequencies transmits mechanical vibrational energy from the horn 200 to the suture retainer 178. This ultrasonic vibrational energy is converted into heat energy and results in a heating of the suture retainer 178. The heat in the suture retainer tends to be concentrated in the material of the suture retainer at locations adjacent to the passages 190 and 192. When the material of the suture retainer 178 adjacent to the passages 190 and 192 has been heated into a transition temperature range for the material, the material of the suture retainer becomes soft and relatively pliable. However, the material of the suture retainer 178 does not melt and become liquid. The transmission of ultrasonic vibratory energy from the horn 200 to the suture retainer 178 is then interrupted.

**[0162]** The anvils 206 and 208 continue to be pressed against the suture retainer 178 with the forces indicated schematically by the arrows 210 and 212 in FIG. 5. If desired, the force applied against the suture retainer 178 may be increased upon interruption of the transmission of ultrasonic vibratory energy to the suture retainer. The force 210 and 212 applied by the anvils 206 and 208 against the suture retainer 178 is effective to plastically deform the heat softened material of the suture retainer. The force applied by the anvils 206 and 208 collapses the passages 190 and 192 and presses the softened material of the suture retainer 178 against the sections 182 and 184 of the suture 176.

**[0163]** The suture retainer 178 and suture 176 may be formed of many different materials. However, it is believed that it will be preferred to form the suture retainer 178 and the suture 176 of a biodegradable polymer. The biodegradable polymer may advantageously be an amorphous thermoplastic. A bonding of the material of the suture retainer 178 with the material of the suture 176 is promoted by forming the suture retainer and suture of the same material. However, the suture retainer 178 and suture 176 could be formed of different materials having similar chemical properties and which are compatible with each other.

**[0164]** In the embodiment of the invention illustrated in FIG. 5, the material of the suture retainer 178 is heated by the application of ultrasonic vibratory energy to the suture retainer by the horn 200. However, it is contemplated that heat energy could be directly transmitted to the suture retainer 178 during the transmission of ultrasonic vibratory energy to the suture retainer if desired. To effect the transmission of heat energy to the suture retainer 178, heating elements could be provided in the anvils 206 and 208.

**[0165]** Referring to FIG. 29, another embodiment of the suture retainer illustrated in FIGS. 1-5 includes substantially flat edges 730, having a non-circular cross section when viewed from the top or the bottom surface. The removal of material, which creates the non-circular shape can help make the suture retainer better remain against smaller surfaces. In this regard, the top and/or bottom surface can include a convex or concave surface.

#### **Embodiment of FIG. 6**

**[0166]** In the embodiment of the invention illustrated in FIGS. 1-5, the suture retainer has a generally spherical configuration and is formed as one piece. In the embodiment of the invention illustrated in FIG. 6, the suture retainer is formed as two pieces. Since the suture retainer of FIG. 6 is similar to the suture retainers of FIGS. 1-5, similar terminology will be utilized to identify similar components. It should be understood that one or more features of other embodiments of the invention disclosed herein could be used with the embodiment of the invention illustrated in FIG. 6.

[0167] A tissue securing system 218 (FIG. 6) is used in a sterile, operating room environment and includes a suture retainer 220 and suture 228. The suture retainer 220 includes two sections, that is, a left (as viewed in FIG. 6) section 222 and a right section 224. The left and right sections 222 and 224 of the suture retainer 220 are formed separately from each other. However, it is contemplated that the two sections 222 and 224 could be interconnected by a flexible connector section. The flexible connector section may be formed as one piece with the left section 222 and the right section 224 of the suture retainer 220.

[0168] A suture 228 includes sections 230 and 232 which are formed separately from the sections 222 and 224 of the suture retainer 220.. The suture 228 is positioned relative to human body tissue 234 with the sections 230 and 232 extending away from an outer side surface 236 of the body tissue. The suture 228 may be connected with the body tissue 234 in the same manner as illustrated schematically in FIG. 1 if desired.

[0169] Although the suture 228 has been illustrated schematically in FIG. 6 in association with soft body tissue 234, it is contemplated that the suture could be associated with hard body tissue or with both hard and soft body tissue. It is also contemplated that the suture 228 could extend through a suture anchor which is disposed in engagement with a surface of the body tissue or embedded in the body tissue.

[0170] The left section 222 of the suture retainer 220 has a generally rectangular configuration. The left section 222 of the suture retainer 220 includes a pair of parallel grooves 240 and 242. The grooves 240 and 242 extend inward, that is, toward the left as viewed in FIG. 6, from a flat major side surface 244 of the left section 222 of the suture retainer 220. The grooves 240 and 242 are each formed as a portion of a cylinder.

[0171] Each of the grooves 240 and 242 has an extent which is slightly less than one-half of the circumferential extent of a cylinder. The radius of the grooves 240 and 242 is the same as the radius of the suture sections 230 and 232. Since the grooves 240 and 242 have side surfaces which are formed as a portion of a cylinder and have an extent which is slightly less than one-

half of the diameter of the cylinder, less than half of each of the suture sections 230 and 232 is disposed in a groove 240 and 242.

[0172] The right section 224 of the suture retainer 222 has a configuration which is the same as the configuration of the left section 222. Thus, the right section 224 of the suture retainer 220 includes a pair of grooves 248 and 250. The grooves 248 and 250 extend inward, that is toward the right, as viewed in FIG. 6, from a flat major side surface 252 of the right section 224 of the suture retainer 220.

[0173] The grooves 248 and 250 are each formed as a portion of a cylinder. However, the grooves 248 and 250 have an extent which is slightly less than one-half the circumferential extent of the cylinder. The grooves 248 and 250 have a radius which is the same as the radius of the suture sections 230 and 232.

[0174] In one specific embodiment of the invention, the identical left and right sections 222 and 224 had a rectangular configuration. The major side surfaces 244 and 252 had a length, as measured transversely to the grooves 240, 242, 248 and 250, of approximately 0.236 inches. The major side surfaces 244 and 252 had a width, as measured parallel to the grooves 240, 242, 248 and 250, of approximately 0.119 inches. The left and right sections 222 and 224 had a thickness, as measured perpendicular to the major side surfaces 244 and 252, of approximately 0.055 inches. The grooves 240, 242, 248, and 250 had a radius of approximately 0.046 inches. The depths of the grooves 240, 242, 248 and 250 was approximately 0.005 inches less than the radius of the grooves or about 0.041 inches.

[0175] It should be understood that the foregoing dimensions for one specific preferred embodiment of the suture retainer 222 have been set forth herein for purposes of clarity of description. It is contemplated that the sections 222 and 224 of the suture retainer 220 will be constructed with dimensions which are substantially different from the specific dimensions which have been set forth herein.

**[0176]** The two sections 222 and 224 of the suture retainer 220 may be formed of many different materials. However, it is believed that it will be preferred to form the sections 222 and 224 of the suture retainer 220 of a biodegradable polymer. The two sections 222 and 224 of the suture retainer 220 may be formed of an amorphous thermoplastic material. The suture 228 and the suture retainer 220 may be formed of any of the materials previously mentioned herein or other materials. The suture 228 and the suture retainer 220 may be formed from the same material or from different materials having the same or similar chemical properties which are compatible with each other.

**[0177]** When the suture 228 and suture retainer 220 are to be used to secure the human body tissue 234, the suture 228 is positioned relative to the body tissue. The suture 228 may be positioned relative to the body tissue in the manner illustrated schematically in FIG. 1. Alternatively, the suture 228 may be connected with one or more suture anchors. A predetermined tension force is then applied to the sections 230 and 232 of the suture.

**[0178]** The two sections 222 and 224 of the suture retainer 220 are positioned in engagement with the sections 230 and 232 of the suture 228. The suture retainer 220 is pressed against the body tissue 234 with a predetermined force. This results in the body tissue being pressed between the suture retainer 220 and the portion of the suture connected with the body tissue 234. A force distribution member could be provided between the suture retainer 220 and body tissue 234 if desired.

**[0179]** The left section 222 of the suture retainer 220 is positioned in abutting engagement with the sections 230 and 232 of the suture 228 and with the body tissue 234 in the manner illustrated schematically in FIG. 6. The right section 224 of the suture retainer 220 is moved into engagement with the sections 230 and 232 of the suture 228 and is also pressed against the body tissue 234. At this time, the major side surface 252 on the right section 224 of the suture retainer 220 is spaced from and extends parallel to the major side surface 244 on the right section 222 of the suture retainer 220. The two sections 222 and 224 of the suture retainer 220 are spaced apart by a distance which is a function of the extent by which the diameters of the suture sections 230 and 232 exceed the combined depth of the grooves 240 and 248 and the

combined depth of the grooves 242 and 250 in the sections 222 and 224 of the suture retainer 220.

**[0180]** In the specific example for which dimensions have been set forth herein, the major side surface 244 of the left section 222 of the suture retainer 220 is spaced 0.010 inches from the major side surface 252 of the right section 224 of the suture retainer 220. It should be understood that a different spacing could be provided between the major side surfaces 244 and 252 of the suture sections 222 and 224 when the grooves 240 and 242 in the suture section 222 are in engagement with the suture sections 230 and 232 and the grooves 248 and 250 in the right suture section 224 are in engagement with the suture sections 230 and 232.

**[0181]** In order to bond the sections 222 and 224 of the suture retainer 220 to each other and to the sections 230 and 232 of the suture 228, ultrasonic vibratory energy is transmitted to the suture retainer 220. At this time, the suture retainer 228 is pressed against the body tissue 234 with a predetermined force and the sections 230 and 232 of the suture 228 are tensioned with a predetermined force.

**[0182]** To effect the transmission of ultrasonic vibratory energy to the sections 222 and 224 of the suture retainer 220, an anvil 258 is moved into engagement with the left section 222 of the suture retainer 220. A horn or acoustic tool 260 is moved into engagement with the right section 224 of the suture retainer 220. The anvil 258 and horn 260 are pressed against the sections 222 and 224 of the suture retainer 220 with a predetermined force to firmly press the sections of the suture retainer against the sections 230 and 232 of the suture 228.

**[0183]** While the anvil 258 and horn 260 are being pressed against the suture retainer sections 222 and 224 with a predetermined force, ultrasonic vibrations are transmitted from the horn 260 to the suture retainer 220. The ultrasonic vibrations transmitted from the horn 260 to the suture retainer 220 have a frequency in excess of 20 kilohertz. The ultrasonic vibrations transmitted to suture retainer 220 by the horn 260 may have a frequency of between 20 kilohertz and 70 kilohertz. It is believed that it may be preferred to transmit ultrasonic vibrations having a frequency close to or greater than 70 kilohertz to the suture retainer 220 from the horn 260.

**[0184]** The ultrasonic vibrations transmitted to the suture retainer 220 create frictional heat and cause portions of the material of the suture retainer 220 to be heated into the transition temperature range for the material. As the material of the suture retainer 220 is heated into its transition temperature range, the material loses some of its rigidity and softens. The material of the suture retainer 220 does not melt and become liquid. The heat in the suture retainer 220 will tend to be concentrated adjacent to the grooves 240, 242, 248 and 250 and adjacent to the major side surfaces 244 and 252.

**[0185]** As the material of the suture retainer 220 is heated and softened by the ultrasonic vibratory energy, the sections 222 and 224 of the suture retainer 220 are pressed together by force applied against the sections of the suture retainer by the anvil 258 and horn 260. As this occurs, the material of the sections 222 and 224 of the suture retainer 220 is plastically deformed and pressed against the sections 230 and 232 of the suture 228 at the grooves 240, 242, 248 and 250 in the suture retainer. At the same time, at least portions of the major side surfaces 248 and 252 on the sections 222 and 224 of the suture retainer 220 will move into engagement with each other.

**[0186]** When this has occurred, the transmission of ultrasonic energy to the suture retainer 228 is interrupted. However, the force applied against the sections 222 and 224 is maintained. It is believed that it may be desired to increase the force applied against the sections 222 and 224 of the suture retainer 220 by the anvil 258 and horn 260 as the application of ultrasonic vibratory energy to the suture retainer 220 is interrupted.

**[0187]** While the clamping force applied by the anvil 258 and horn 260 is maintained, the left and right sections 222 and 224 of the suture retainer 220 bond to each other. In addition, the left and right sections 222 and 224 of the suture retainer 220 bond to the sections 230 and 232 of the suture 228. This results in the suture 228 being firmly gripped by the sections of the suture retainer 220. The sections 222 and 224 of the suture retainer 220 bond to the suture 228 without significant deformation of the suture.

**[0188]** The left and right sections 222 and 224 of the suture retainer 220 bond to each other at a joint formed between the surfaces 244 and 252 of the sections of the suture retainer. This results in a bonding of the sections 222 and 224 of the suture retainer 220 at locations offset to both sides of the suture 228 and at locations offset to both sides of the suture 230. The material of the sections 222 and 224 of the suture retainer 220 defining the grooves 240, 242, 248 and 250 bond to the outer side surfaces of the sections 230 and 232 of the suture 228.

**[0189]** Although it is preferred to heat the sections 222 and 224 of the suture retainer 220 with ultrasonic vibratory energy in the manner previously explained, it is contemplated that heat energy could be directly transmitted to the suture retainer if desired during the transmission of ultrasonic vibratory energy to the suture retainer. The heat energy could be transmitted to the suture retainer 220 from heating coils in the anvil 258 and/or horn 260. If desired, a separate heat application member could be provided.

**[0190]** The sections 222 and 224 of the suture retainer 220 prevent direct engagement of the anvil 258 and horn 260 with the suture 228. This prevents excessive heating of the suture 228.

#### **Embodiment of FIGS. 7 and 8**

**[0191]** In the embodiment of the invention illustrated in FIG. 6, the suture retainer 220 is formed in two sections 222 and 224. In the embodiment of the invention illustrated in FIGS. 7 and 8, the suture retainer is formed as one piece having passages for receiving the sections of the suture. Since the embodiment of the invention illustrated in FIGS. 7 and 8 is generally similar to the embodiment of the invention illustrated in FIGS. 1-6, similar terminology will be utilized to identify similar components. It should be understood that one or more of the features of the other embodiments of the invention illustrated herein could be utilized in association with the embodiment of the invention illustrated in FIGS. 7 and 8.

**[0192]** A tissue securing system 268 is used in a sterile, operating room environment and includes a suture retainer 270 and a suture 280. The suture retainer 270 is integrally formed as

one piece and has a cylindrical configuration. A pair of cylindrical passages 272 and 274 (FIG. 7) extend diametrically through the suture retainer 270. Of course, the suture retainer 270 and passages 272 and 274 could have a different configuration if desired. For example, the suture retainer 270 could have an oval or a polygonal configuration.

[0193] Left and right sections 276 and 278 of a suture 280 extend through the passages 272 and 274. The suture sections 276 and 278 are connected with layers of human body tissue (not shown) in the same manner as has been illustrated schematically in FIG. 1. However, the suture sections 276 and 278 could be connected with a suture anchor embedded in the body tissue. Alternatively, each of the sections 276 and 278 of the suture 280 could be connected with a separate suture anchor, in much the same manner as in which the one section of the suture 112 of FIG. 4 is connected with the suture anchor 120.

[0194] It is contemplated that the suture retainer 270 and suture 280 could be used in association with hard body tissue, soft body tissue, or hard and soft body tissue. The suture retainer 270 and suture 280 may be used with body tissue in any one of the ways previously described herein. Of course, the suture retainer and suture may be used with body tissue in other known ways if desired.

[0195] The suture retainer 270 may be formed of many different materials. However, It is believed that it will be preferred to form the suture retainer 270 of a biodegradable polymer. It is believed that it may be preferred to form both the suture retainer 270 and the suture 280 of the same amorphous thermoplastic material. However, if desired, the suture 280 and suture retainer 270 could be formed of different materials which have the same or similar chemical properties and are compatible with each other. The suture 280 and/or the suture retainer 270 may be formed of either biodegradable or non-biodegradable materials.

[0196] In one specific embodiment of the invention, the cylindrical suture retainer 270 had a diameter of 0.119 inches. This particular suture retainer 270 had an axial extent of 0.236 inches. The passages 272 and 274 each had a diameter of 0.046 inches. If desired, the passages

272 and 274 could be formed with an oval configuration with parallel flat surfaces having a length of 0.030 inches extending between semicircular opposite end portions of the ovals.

**[0197]** It should be understood that the foregoing specific dimensions for embodiments of the suture retainer 270 have been set forth herein for purposes of clarity of description. It is contemplated that the suture retainer 270 can and will be formed with dimensions which are different than these specific dimensions. It is also contemplated that the suture retainer 270 will be constructed with a configuration which is different than the specific configuration illustrated herein. For example, the suture retainer 270 could have a prismatic configuration with the passages 272 and 274 extending between one corner portion and a side surface of the prism.

**[0198]** The suture 280 is positioned relative to body tissue in much the same manner as illustrated in FIG. 1. The sections 276 and 278 of the suture 280 are then inserted through the passages 272 and 274 (FIG. 7). While the suture 280 is tensioned, the suture retainer 270 is moved along the suture toward the body tissue. A predetermined force is transmitted from the suture retainer 270 to the body tissue while the sections 276 and 278 of the suture 280 are tensioned with a predetermined force in the manner previously described in conjunction with the embodiment of the invention illustrated in FIG. 4.

**[0199]** While the body tissue is compressed between the suture 280 and the suture retainer 270, ultrasonic vibratory energy is transmitted to the suture retainer 270. To transmit ultrasonic vibratory energy to the suture retainer 270, an anvil 286 (FIG. 8) and a horn or acoustic tool 288 are pressed against opposite sides of the suture retainer 270 with a predetermined force. The suture 280 is tensioned and the suture retainer 270 is pressed against body tissue with predetermined forces while the anvil 286 and horn 288 are pressed against the suture retainer.

**[0200]** The horn 288 is then vibrated at an ultrasonic frequency, that is, at a frequency greater than 20 kilohertz. The horn 280 may be vibrated at a frequency of between 20 and 70 kilohertz. It is believed that it may be preferred to vibrate the horn 288 at a frequency close to or

greater than 70 kilohertz. As this occurs, vibratory mechanical energy at ultrasonic frequencies is transmitted from the horn 288 to the suture retainer 270.

**[0201]** The ultrasonic vibratory energy transmitted from the horn 288 to the suture retainer 270 is effective to heat the suture retainer. The heat tends to be concentrated in the portion of the suture retainer 270 adjacent to the sections 276 and 278 of the suture 280.

**[0202]** When the portion of the suture retainer 270 adjacent to the sections 276 and 278 of the suture 280 have been heated to a temperature in the transition temperature range for the material of the suture retainer 270, the application of ultrasonic vibratory energy to the suture retainer 270 by the horn 288 is interrupted. When material of the suture retainer 270 is heated into the transition temperature range, the material of the suture retainer becomes soft and pliable. Although the material of the suture retainer 270 does not melt and become liquid, the material of the suture retainer 270 is softened and loses its rigidity when it is heated into the transition temperature range.

**[0203]** The force applied against the suture retainer 270 is then maintained or increased. The force applied against the suture retainer 270 by the anvil 286 and horn 288 is effective to plastically deform the material of the suture retainer. As the heat softened material of the suture retainer 270 is plastically deformed by the anvil 286 and horn 288, the material of the suture retainer is firmly pressed against the sections 276 and 278 of the suture 280.

**[0204]** As the heated and softened material of the suture retainer 270 cools, the material of the suture retainer bonds to the suture 280. This results in the suture retainer 270 securely gripping the sections 276 and 278 of the suture 280. The suture 280 is not significantly deformed as the suture retainer 270 is heated and bonded to the suture. Therefore, the strength of the suture 280 is not significantly reduced.

**[0205]** In the foregoing description, the suture retainer 270 was heated by the application of ultrasonic vibratory energy to the suture retainer. It is contemplated that heat energy could be transmitted to the suture retainer 270 along with the ultrasonic vibratory energy. This could be

accomplished in many different ways. For example, a heating element could be provided in the anvil 286 and/or horn 288. Alternatively, a separate heating element could be moved into contact with the suture retainer 270.

#### **Embodiment of FIG. 9**

[0206] In the embodiment of the invention illustrated in FIGS. 7 and 8, the suture 280 extends through passages 272 and 274 formed in the suture retainer 270. In the embodiment of the invention illustrated in FIG. 9, the suture is wrapped around a section of the suture retainer and is engaged by other sections of the suture retainer. Since the suture retainer of the embodiments of the invention illustrated in FIGS. 1-8 is similar to the suture retainer of the embodiment of the invention illustrated in FIG. 9, similar terminology will be utilized to identify similar components. It should be understood that one or more features of other embodiments of the invention disclosed herein may be used with the embodiment of the invention illustrated in FIG. 9.

[0207] A tissue securing system 291 is used in a sterile, operating room environment and includes a suture retainer 292 and a suture 302. The suture retainer 292 includes a cylindrical central section 294 which is disposed between left and right side sections 296 and 298. The central section 294 is formed separately from the side sections 296 and 298. The side sections 296 and 298 are formed separately from each other. However, the side sections 296 and 298 could be interconnected if desired. For example, the side sections 296 and 298 could be integrally formed as one piece with a flexible connector section which extends between the side sections. Alternatively, the central section 294 and side sections 296 and 298 could be formed as one piece.

[0208] A suture 302 is wrapped around the central section 294. The suture 302 is received in a groove 304 in the central section 294. The groove 304 has a circular configuration and has a central axis which is coincident with a central axis of the cylindrical central section 294.

[0209] The groove 304 has an extent which is greater than 360° and extends completely around the central section 294 of the suture retainer 292. The groove 304 is formed as a portion of a helix. Opposite end portions of the groove 304 are disposed in an overlapping relationship on the central portion 294 of the suture retainer 292. The suture 302 is disposed in the groove 304 throughout the extent of its engagement with the central section 294.

[0210] Although the groove 304 has been shown as having somewhat more than a single turn in FIG. 8, the groove could have a plurality of turns around the central section 294 of the suture retainer 292 if desired. If this was done, the suture 302 would be wrapped a plurality of times around the central section 294. Thus, rather than having a single wrap of the suture 302 around the central section 294 of the suture retainer 292 in the manner illustrated in FIG. 9, the suture 302 could be wrapped a plurality of times around the central section of the suture retainer 294.

[0211] The suture 302 and suture retainer 292 may be formed of the same material or different materials. Similarly, the central section 294 and side sections 296 and 298 may be formed of the same material or different materials. It is believed that it may be preferred to form the suture 302 and the suture retainer 294 from biodegradable materials. However, the suture 302 and/or the suture retainer 292 could be formed of materials which are not biodegradable. It may also be preferred to form the suture retainer 292 and suture 302 of an amorphous polymeric material. The suture retainer 292 and suture 302 may be formed of any of the materials previously mentioned herein or other materials.

[0212] When the suture retainer 292 is to be utilized to secure human body tissue, the suture 302 is positioned relative to the body tissue in the manner illustrated in FIG. 4. Of course, the suture 302 could be positioned relative to body tissue in a different manner if desired. The suture 302 and suture retainer 292 may be used with hard, soft, or hard and soft body tissue.

[0213] The suture 302 is wrapped around the central section 294 of the suture retainer, in the manner illustrated schematically in FIG. 9. Once the suture 302 has been wrapped around

the central section 294 of the suture retainer 292, the central section of the suture retainer is moved along the suture 302 toward the body tissue.

**[0214]** As the central section 294 of the suture retainer 292 moves toward the body tissue, a wrap or turn of the suture 302 around the central section of the suture retainer moves along the suture toward the body tissue. The central section 294 of the suture retainer 292 may be moved along a straight path toward the body tissue without rotating while tension is maintained in the suture 302 and the suture slides along the groove 304 in the central section of the suture retainer. Alternatively, the central section 294 of the suture retainer could be rolled along the suture 302 toward the body tissue.

**[0215]** The central section 294 of the suture retainer 292 is moved along the suture 302 until the central section of the suture retainer engages the body tissue in the manner illustrated in FIG. 4 or engages a force distribution member in the manner illustrated in FIG. 5. A predetermined tension force is then applied to the suture 302 and the central section 294 of the suture retainer is urged toward the body tissue with a predetermined force. The body tissue engaged by the suture 302 is compressed between the central section 294 of the suture retainer 292 and a suture anchor, similar to the suture anchor 120 of FIG. 4.

**[0216]** While the suture 302 is tensioned with a predetermined force and a predetermined force is transmitted from the central section 294 of the suture retainer 292 to the body tissue, the side sections 296 and 298 are aligned with the central section 294 of the suture retainer. The side sections 296 and 298 have concave surfaces 310 and 312 which are pressed against the turn in the suture 302 which extends around the central portion 294 of the suture retainer 292. The surfaces 310 and 312 have an arc of curvature which is the same as the arc of curvature of a generally cylindrical outer side surface 314 on the side sections 296 and 298. However, since the suture 302 projects out of the groove 304, the side surfaces 310 and 312 on the side sections 296 and 298 are slightly spaced from the side surface 314 on the central section 294 of the suture retainer 292.

**[0217]** In accordance with a feature of the present invention, ultrasonic vibratory energy is applied to the suture retainer 292. To apply the ultrasonic vibratory energy to the suture retainer 292, a support member or anvil 320 is pressed against the side section 296 of the suture retainer 292. A horn or acoustic tool 322 is pressed against the side section 298 of the suture retainer 292. The anvil 320 and horn 322 are pressed against the opposite side sections 296 and 298 of the suture retainer 292 with a predetermined force.

**[0218]** While the suture retainer 292 is clamped between the anvil 320 and horn 322, mechanical vibrations at an ultrasonic frequency are transmitted from the horn 322 to the suture retainer 292. The ultrasonic vibratory energy is transmitted from the horn 322 to the suture retainer 292 at frequency above 20 kilohertz. The horn 322 may transmit the ultrasonic vibratory energy to the suture retainer 292 at a frequency between 20 kilohertz and 70 kilohertz. It is contemplated that it may be desired to have the ultrasonic vibratory energy transmitted to the suture retainer at a frequency close to or greater than 70 kilohertz. However, it should be understood that the ultrasonic vibratory energy could be transmitted to the suture retainer 292 at any desired frequency above the frequency normally detected by the human ear, that is above approximately 20 kilohertz.

**[0219]** The ultrasonic vibratory energy transmitted to the suture retainer 292 is converted into heat. The heat tends to concentrate at the joints between the side sections 296 and 298 and central section 294 of the suture retainer 292. This results in the material forming the side sections 296 and 298 and the central section 294 of the suture retainer 292 being heated into the transition temperature range of the material forming the suture retainer. The application of the ultrasonic vibratory energy to the suture retainer 292 by the horn 322 is then interrupted.

**[0220]** As the material of the suture retainer 292 is heated into its transition temperature range, the material loses its rigidity and softens. The anvil 320 and horn 322 apply force against the suture retainer 292 to plastically deform the material of the suture retainer. The softened side surfaces 310 and 312 on the side sections 296 and 298 are pressed against and are indented by the suture 302. As this occurs, the softened side surfaces 310 and 312 of the side sections 296

and 298 move into engagement with the softened side surface 314 on the central section 294 of the suture retainer 292.

[0221] Although the application of ultrasonic vibratory energy to the suture retainer 292 is interrupted, the anvil 320 and horn 322 continue to be pressed against the side sections 296 and 298 of the suture retainer 292 with a predetermined force. If desired, the force with which the anvil 320 and horn 322 are pressed against the suture retainer 292 can be increased as the transmission of ultrasonic vibratory energy to the suture retainer is interrupted.

[0222] As the material of the suture retainer 292 cools, the side sections 296 and 298 are bonded to the central section 294 of the suture retainer 292. In addition, the suture 302 is bonded to the central section 294 and to the side sections 296 and 298 of the suture retainer 292.

[0223] The groove 304 in the central section 294 of the suture retainer 292 is deep enough to prevent significant deformation and loss of strength of the suture 302. As the heat softened material of the side sections 296 and 298 of the suture retainer is pressed against the suture 302, the material of the side sections is plastically deformed.

[0224] It is contemplated that a of the suture 302 with the central section 294 and side sections 296 and 298 of the suture retainer 292 may be promoted by forming the suture and the sections of the suture retainer of the same material. The material may be an amorphous thermoplastic which is biodegradable.

[0225] If desired, the groove 304 could be omitted from the central section 294 of the suture retainer 292. Alternatively, the groove 304 could be deepened so that the groove has a depth which is equal to or slightly greater than the diameter of the suture 302. If desired, the groove 304 could be formed with an undercut configuration so that the portion of the suture 302 in the groove 304 is not exposed to the side sections 296 and 298 of the suture retainer 292. If this was done, the suture 302 would be bonded to only the central section 294 of the suture retainer 292 and would not be bonded to the side sections 296 and 298 of the suture retainer.

**[0226]** If the configuration of groove 304 is changed to an undercut configuration, the suture 302 would be completely enclosed by the groove. A groove having this configuration is disclosed in U.S. Patent No. 6,010,525 which has been and hereby is incorporated herein in its entirety. If the groove 304 has such an undercut configuration, the side sections 296 and 298 could be eliminated. The anvil 320 and horn 322 would then be pressed against opposite sides of the cylindrical outer side surface 314 of the central section 294 in the same manner as is disclosed in FIG. 8 in association with the suture retainer 270. As is disclosed in the aforementioned U.S. Patent No. 6,010,525, the groove and suture could extend for a plurality of turns around the central portion 294 of the suture retainer 292.

**[0227]** In the foregoing description, it has been assumed that only ultrasonic vibrational energy may be transmitted to the suture retainer 292 to effect a securing of the suture 302 by the suture retainer 292. However, thermal energy in the form of heat could be directly applied to the suture retainer 292 if desired. This could be accomplished in many different ways. For example, a heating element could be provided in the anvil 320 and/or the horn 322.

#### **Embodiment of FIGS. 10 and 11**

**[0228]** In the embodiment of the invention illustrated in FIG. 9, the suture 302 is wrapped around a central section 294 of the suture retainer 292. In the embodiment of the invention illustrated in FIGS. 10 and 11, sections of the suture extend through passages in a central section of the suture retainer. Since the embodiment of the invention illustrated in FIGS. 10 and 11 is generally similar to the embodiments of the invention illustrated in FIGS. 1-9, similar terminology will be utilized to identify similar components. It should be understood that one or more of the features of the other embodiments of the invention disclosed herein could be used with the embodiment of the invention illustrated in FIGS. 10 and 11 if desired.

**[0229]** A tissue securing system 328 is used in a sterile, operating room environment and includes a suture 330 and suture retainer 340. The suture 330 (FIGS. 10 and 11) has a pair of sections 332 and 334 which are connected with human body tissue. The sections 332 and 334 of the suture 330 may be connected with body tissue in the manner illustrated schematically in FIG. 1.

The sections 332 and 334 of the suture 330 extend through a central section 338 of the suture retainer 340 (FIG. 11). In addition to the central section 338, the suture retainer 340 includes a pair of side sections 342 and 344.

**[0230]** The central section 338 and side sections 342 and 344 all have rectangular configurations. However, the central and side sections 338, 342 and 344 (FIG. 11) could have a different configuration if desired. The central section 338 is thinner (as viewed in FIG. 11) than the side sections 342 and 344. The sections 332 and 334 of the suture 330 extend through cylindrical passages 348 and 350 in the central section 338.

**[0231]** The relatively thin central section 338 and the relatively thick side sections 342 and 344 of the suture retainer 340 are formed of a biodegradable material. The suture 330 is also formed of a biodegradable material. The suture 330 and suture retainer 340 may be formed of the same biodegradable material. It may be preferred to form the suture 330 and suture retainer 340 of an amorphous polymer. If desired, the suture 330 and suture retainer 340 could be formed of different materials which are compatible and have the same or similar chemical properties. The suture 330 and suture retainer 340 may be formed of any of the materials previously mentioned herein or of other known materials.

**[0232]** When the suture 330 and suture retainer 340 are to be used to secure human body tissue, the sections 332 and 334 of the suture 330 are positioned relative to body tissue in a manner similar to that disclosed in FIG. 1. The sections 332 and 334 of the suture 330 are then inserted through the passages 348 and 350 in the central section 338 of the suture retainer 340. While the suture 330 is tensioned, the central section 338 of the suture retainer 340 is moved along the suture toward the body tissue.

**[0233]** The central section 338 of the suture retainer 340 is pressed against either the body tissue in the manner illustrated schematically in FIG. 4 or against a force distribution member in the manner illustrated schematically in FIG. 5. While a predetermined force is transmitted from the central section 338 of the suture retainer 340 to the body tissue and while the sections 332 and 334 of the suture 330 are tensioned with a predetermined force, the thick

side sections 342 and 344 of the suture retainer 340 are positioned in engagement with opposite sides of the thin central section 338, in the manner illustrated in FIG. 11.

**[0234]** An apparatus for transmitting ultrasonic vibratory energy to the suture retainer 340 is then moved into engagement with the side sections 342 and 344 of the suture retainer. The apparatus for applying ultrasonic vibratory energy to the suture retainer 340 includes an anvil or support portion 354 and a horn or acoustic tool 356. The anvil 354 and horn 356 are pressed against opposite sides of the suture retainer with a predetermined force. While the suture retainer 340 is clamped between the anvil 354 and horn 356, ultrasonic vibratory energy is transmitted from the horn 356 to the suture retainer 340.

**[0235]** The ultrasonic vibratory energy transmitted from the horn 356 to the suture retainer 340 is effective to heat the material of the suture retainer. The heat tends to be concentrated at the joints between the thick side sections 342 and 344 and the thin central section 338 of the suture retainer 340. In addition, the heat tends to be concentrated at the joint between the sections 332 and 334 of the suture and the central section 338 of the suture retainer. This results in a substantial portion of the material of the thin central section 338 of the suture retainer 340 being heated into its transition temperature range.

**[0236]** As the material of the suture retainer 340 is heated into its transition temperature range, the material of the suture retainer loses its rigidity and becomes soft. However, the material of the suture retainer is not heated enough to melt the material of the suture retainer. Since the central section 338 is relatively thin, the material of the central section becomes very pliable while the side sections 342 and 344 still have some rigidity.

**[0237]** Once a substantial portion of the material of the central section 338 of the suture retainer 340 has been softened by being heated into its transition temperature range, the transmission of ultrasonic vibratory energy from the horn 356 to the suture retainer 340 is interrupted. However, the anvil 354 and horn 356 continue to apply force against opposite sides of the suture retainer 340. The magnitude of the force applied against opposite sides of the suture retainer 340 by the anvil 354 and horn 356 may be increased as the transmission of

ultrasonic vibratory energy from the horn 356 to the suture retainer 340 is interrupted. The force applied against opposite sides of the suture retainer 340 by the anvil 354 and horn 356 is effective to plastically deform the heat softened material of the suture retainer 340.

**[0238]** As the suture retainer 340 cools, the side sections 342 and 344 of the suture retainer are bonded to the central section 338 of the suture retainer. In addition, the central section 338 of the suture retainer 340 is bonded to the sections 332 and 334 of the suture 330. This results in the suture 330 being securely gripped by the suture retainer 340. However, there is no significant deformation of the suture 330 so that the strength of the suture 330 is not significantly reduced.

**[0239]** In the foregoing description, the material of the central section 338 of the suture retainer 340 was heated by the transmission of ultrasonic vibratory energy to the suture retainer 340. However, it is contemplated that thermal energy could be applied to the suture retainer 340 along with the ultrasonic vibratory energy. This could be accomplished by providing a heating element in the anvil 354 and/or horn 356. Alternatively, a separate member could be utilized to apply heat directly to the suture retainer 340.

**[0240]** The anvil 354 and horn 356 engage only the suture retainer 340. The anvil 354 and horn 356 are maintained in a spaced apart relationship with the suture 330. This prevents excessive heating and/or deformation of the suture.

#### **Embodiment of FIGS. 12 and 13**

**[0241]** In the embodiment of the invention illustrated in FIGS. 10 and 11, the sections of the suture extend through passages in a central section of the suture retainer. In the embodiment of the invention illustrated in FIGS. 12 and 13, the sections of the suture are disposed in grooves formed in the central section of the suture retainer. Since the embodiment of the invention illustrated in FIGS. 12 and 13 is generally similar to the embodiments of the invention illustrated in FIGS. 1-11, similar terminology will be utilized to designate similar components. It should be

understood that one or more of the features of other embodiments of the invention disclosed herein could be used with the embodiment of the invention illustrated in FIGS. 12 and 13.

**[0242]** A tissue securing system 359 (FIGS. 12 and 13) is used in a sterile, operating room environment and includes a suture 360 and a suture retainer 368. The suture 360 has left and right sections 362 and 364. The sections 362 and 364 of the suture 360 are connected with human body tissue in a manner similar to the manner illustrated schematically in FIG. 1. However, the sections 362 and 364 of the suture 360 could be connected with body tissue in a different manner if desired. For example, the sections 362 and 364 could be connected with a suture anchor embedded in the body tissue. Alternatively, a separate suture anchor could be provided for each of the sections 362 and 364 of the suture 360.

**[0243]** A suture retainer 368 includes a central section 370. A pair of side sections 372 and 374 are disposed on opposite sides of the central section 370. The central section 370 and side sections 374 all have a generally rectangular configuration. However, the central section 370 is thinner than the side sections 372 and 374 (FIG. 13).

**[0244]** A pair of grooves 378 and 380 are provided in the central section 370. The grooves 378 and 380 have parallel longitudinal central axes. The grooves 378 and 380 are disposed in opposite sides of the central section 370 and open in opposite directions.

**[0245]** In addition, a groove 384 is formed in the side section 372. The groove 384 extends parallel to and is aligned with the groove 380 in the central section 370. Similarly, a groove 386 is formed in the side section 374. The groove 386 extends parallel to and is aligned with the groove 378 in the central section 370. The section 362 of the suture 360 is received in the grooves 378 and 386 (FIG. 13). Similarly, the section 364 of the suture 360 is received in the grooves 380 and 384.

**[0246]** The grooves 378 and 386 are aligned with each other and are offset to one side of the grooves 380 and 384. This results in the sections 362 and 364 of the suture 360 being offset from each other (FIG. 13). However, if desired, the grooves 378 and 386 and the grooves 380

and 384 could all be aligned. This would result in the sections 362 and 364 of the suture being aligned with each other.

**[0247]** The central section 370 and side sections 372 and 374 of the suture retainer 368 are formed of a biodegradable material. The suture 360 is also formed of a biodegradable material. The suture 360 and suture retainer 368 may be formed of the same biodegradable material. It may be preferred to form the suture 360 and suture retainer 368 of an amorphous polymer. If desired, the suture 360 and suture retainer 368 could be formed of different materials which are compatible and have the same or similar chemical properties. It is contemplated that the suture 360 and suture retainer 368 could be formed of any of the materials previously mentioned herein or of other materials.

**[0248]** The suture 360 is positioned relative to body tissue in the same manner as is illustrated schematically in FIG. 1. While the sections 362 and 364 of the suture are tensioned with a predetermined force, the central section 370 of the suture retainer 368 is positioned relative to the sections 362 and 364 of the suture 360. In addition, the side sections 372 and 374 are positioned relative to the sections 362 and 364 of the suture and relative to the central section 370. The central section 370 and side sections 372 and 374 of the suture retainer 368 are urged toward the body tissue in the manner illustrated schematically in FIG. 4. This results in the transmission of a predetermined force from the suture retainer 360 to the body tissue while the sections 362 and 364 of the suture 360 are tensioned with a predetermined force.

**[0249]** In accordance with one of the features of the present invention, ultrasonic vibratory energy is then transmitted to the suture retainer 368. To transmit ultrasonic vibratory energy to the suture retainer 368, an anvil or support member 390 (FIG. 13) is pressed against the side section 372 of the suture retainer 368. In addition, a horn or acoustic tool 392 is pressed against the side section 374 of the suture retainer 368. While the suture retainer 368 is clamped between the anvil 390 and horn 392, ultrasonic vibratory energy is transmitted from the horn to the suture retainer.

**[0250]** The ultrasonic vibratory energy transmitted from the horn 392 to the suture retainer 368 may have a frequency in a range between 20 kilohertz and 70 kilohertz. It is believed that it will be preferred to transmit ultrasonic vibratory energy having a frequency of approximately 70 kilohertz or more from the horn 392 to the suture retainer 368.

**[0251]** The ultrasonic vibratory energy is effective to heat the suture retainer 368. The heat is concentrated at the joints between the thin central section 370 and thick side sections 372 and 374 of the suture retainer 368. Since the central section 370 is thinner than the side sections 372 and 374, a substantial percentage of the material of the central section 370 is heated into its transition temperature range while a smaller percentage of the material of the side sections 372 and 374 is heated into its transition temperature range.

**[0252]** Heating the material of the suture retainer 368 into the transition temperature range is effective to cause the material of the suture retainer to soften and lose its rigidity. Although the material of the suture retainer 368 softens, the material does not melt and become liquid. The softened material of the suture retainer is pliable and plastically deforms under the influence of the clamping force applied by the anvil 390 and horn 392.

**[0253]** As the material of the suture retainer 368 plastically deforms, a flat major side surface 396 on the central section 370 of the suture retainer 368 and a flat side surface 398 on the side section 372 of the suture retainer move into engagement. At the same time, a flat side surface 402 on the central section 370 of the suture retainer 368 and a flat side surface 404 on the side section 374 of the suture retainer move into engagement. As this occurs, the softened material of the central section 370 of the suture retainer 368 is deformed by force applied to the central section through the sections 362 and 364 of the suture 360.

**[0254]** After material of the suture retainer 368 has been heated into its transition temperature range, the application of ultrasonic vibratory energy to the suture retainer is interrupted. However, the force pressing the anvil 390 and the horn 392 against the suture retainer is maintained. If desired, the magnitude of the force applied against the suture retainer

368 by the anvil 390 and horn 392 may be increased simultaneously with the interruption of the application of ultrasonic vibratory energy to the suture retainer.

**[0255]** As the material of the suture retainer 368 cools, the flat major side surface 396 on the central section 370 bonds to the flat major side surface 398 on the side section 372. In addition, the flat major side surface 402 on the central section 370 bonds to the flat major side surface 404 on the side section 374. The surfaces defining the grooves 378 and 380 in the central section 370 of the suture retainer 368 bond to the sections 362 and 364 of the suture 360. The surfaces defining the grooves 384 and 386 in the side sections 372 and 374 of the suture retainer 368 also bond to the sections 362 and 364 of the suture 360.

**[0256]** In the foregoing description, the suture retainer 368 was heated by the application of ultrasonic vibratory energy to the suture retainer. It is contemplated that the suture retainer 368 could also be heated by the direct application of thermal energy to the suture retainer. If this is to be done, a heating element could be provided in the anvil 390 and/or horn 392. If desired, a separate heating element could be moved into engagement with the suture retainer to transmit heat to the suture retainer.

**[0257]** The anvil 390 and horn 392 engage only the suture retainer 368. The anvil 390 and horn 392 are maintained in a spaced apart relationship with the suture 360. This prevents excessive heating and/or deformation of the suture 360.

#### **Embodiment of FIGS. 14 and 15**

**[0258]** In the embodiment of the invention illustrated in FIGS. 12 and 13, straight sections 362 and 364 of the suture 360 are connected with the suture retainer 368. In the embodiment of the invention illustrated in FIGS. 14 and 15, sections of the suture are wrapped around a portion of the suture retainer. Since the embodiment of the invention illustrated in FIGS. 14 and 15 is generally similar to the embodiments of the invention illustrated in FIGS. 1-13, similar terminology will be utilized to describe similar components. It should be understood

that one or more of the features of other embodiments of the invention could be utilized in association with the embodiment of the invention illustrated in FIGS. 14 and 15 if desired.

**[0259]** A tissue securing system 408 (FIG. 15) is used in a sterile, operating room environment and includes a suture 410 and a suture retainer 418. The suture 410 includes left and right sections 412 and 414. The left and right sections 412 and 414 of the suture 410 are connected with human body tissue in the manner illustrated schematically in FIG. 1. Alternatively, the left and right sections 412 and 414 of the suture 410 could be connected with a single suture anchor. If desired, a suture anchor could be provided in association with each of the sections 412 and 414 of the suture 410.

**[0260]** The suture retainer 418 (FIG. 15) includes a central section 420 and a pair of side sections 422 and 424. The central section 420 and side sections 422 and 424 of the suture retainer 418 are formed of a biodegradable material. The suture 410 is also formed of a biodegradable material. The suture 410 and suture retainer 418 may be formed of the same biodegradable material. It may be preferred to form the suture 410 and suture retainer 418 of an amorphous polymer. If desired, the suture 410 and suture retainer 418 could be formed of different materials having the same or substantially similar chemical properties. The suture 410 and suture retainer 418 could be formed of any of the materials previously mentioned herein or other materials.

**[0261]** When the suture retainer 418 is to be utilized to secure body tissue, the suture sections 412 and 414 are wrapped around the central section 420 of the suture retainer in the manner illustrated schematically in FIG. 14. While the sections 412 and 414 of the suture 410 are tensioned, the central section 420 of the suture retainer is moved along the suture 410 toward the body tissue. Of course, the turns or wraps formed around the central section 420 of the suture retainer 418 are moved toward the body tissue along with the central section.

**[0262]** The central section 420 of the suture retainer is moved into engagement with the body tissue or with a force distribution member in the manner similar to that illustrated in either FIG. 4 or FIG. 5. While a predetermined force is transmitted from the central section 420 of the

suture retainer to the body tissue, the sections 412 and 414 of the suture 410 are tensioned with a predetermined force. This results in the body tissue being compressed under the influence of force being transmitted to the body tissue from the central section 420 of the suture retainer 418 and from the suture 410.

[0263] While the suture is being tensioned with a predetermined force and while the predetermined force is being transmitted from the central section 420 of the suture retainer 418, the side sections 422 and 424 are moved into juxtaposition with the central section 420 of the suture retainer 418. The side sections 422 and 424 are thicker than the central section 420. Force is also transmitted from the side sections 422 and 424 to the body tissue.

[0264] To effect the application of ultrasonic vibratory energy to the suture retainer 418, and anvil or support portion 428 is pressed against the relatively thick side section 422 of the suture retainer 418. At the same time, a horn or acoustic tool 430 is pressed against the relatively thick side section 424 of the suture retainer 418. This results in the suture retainer 418 being clamped between the anvil 428 and horn 430 with a predetermined force. The clamping force presses the suture 410 against the relatively thin central section 420 of the suture retainer.

[0265] While maintaining the predetermined clamping force on the suture retainer 418, ultrasonic vibratory energy is transmitted from the horn 430 to the suture retainer. The ultrasonic vibratory energy is transmitted at a frequency of between 20 kilohertz and 70 kilohertz. It is believed that it may be preferred to transmit the ultrasonic vibratory energy at a frequency close to or greater than 70 kilohertz.

[0266] The ultrasonic vibratory energy is effective to heat the suture retainer 418. The heat tends to be concentrated at the joints between the thin central section 420 and thick side sections 422 and 424 of the suture retainer 418. Since the central section 420 of the suture retainer 418 is thinner than the side sections 422 and 424 of the suture retainer, a larger percentage of the material of the central section 420 of the suture retainer 418 is heated into its transition temperature range by the ultrasonic vibratory energy before a corresponding percentage of the side sections 422 and 424 is heated into the transition temperature range.

**[0267]** When the material of the suture retainer 418 has been heated into its transition temperature range, the material becomes soft and pliable. The clamping force applied against the side sections 422 and 424 causes the turns in the sections 412 and 414 of the suture 410 to indent and plastically deform the heat softened material of the central section 420 and side sections 422 and 424. As this occurs, the side sections 422 and 424 move into abutting engagement with the central section 410 under the influence of the clamping force applied by the anvil 428 and horn 430.

**[0268]** Once the material of the central section 420 and side sections 422 and 424 adjacent to the turns in the sections 412 and 414 of the suture 410 have been heated into the transition temperature range, the application of ultrasonic vibratory energy to the suture retainer 418 is interrupted. However, the clamping force applied against the suture retainer by the anvil 428 and horn 430 is maintained constant or increased as the application of ultrasonic vibratory energy to the suture retainer is interrupted. As the material of the suture retainer 418 cools, while the suture retainer is clamped between the anvil 428 and horn 430, the side sections 422 and 424 of the suture retainer 418 bond to the central section 420 of the suture retainer. In addition, the side sections 422 and 424 and the central section 420 of the suture retainer 418 bond to the suture 410.

#### **Embodiment of FIGS. 16 and 17**

**[0269]** In the embodiments of the invention illustrated in FIGS. 9 through 15, the suture retainer is formed by a plurality of sections which are bonded together. In the embodiment of the invention illustrated in FIGS. 16 and 17, the suture retainer is formed as one piece. Since the suture retainer in the embodiment of FIGS. 16 and 17 is generally similar to the suture retainers of FIGS. 1-16, similar terminology will be utilized to identify similar components. It should be understood that one or more of the features of any of the other embodiments of the invention disclosed herein could be utilized with the embodiment of the invention illustrated in FIGS. 16 and 17.

**[0270]** A tissue securing system 438 is used in a sterile, operating room environment and includes a suture 440 and a suture retainer 448. The suture 440 includes left and right sections 442 and 444. The left and right sections 442 and 444 of the suture 440 are connected with human body tissue in a manner similar to the manner illustrated schematically in FIG. 1. However, the suture 440 could be connected with body tissue in a different manner if desired. For example, the sections 442 and 444 could be connected with a single suture anchor embedded in body tissue. Alternatively, a separate suture anchor could be provided for each of the sections 442 and 444 if desired.

**[0271]** A one-piece suture retainer 448 is formed separately from the suture 440. The suture retainer 448 has a generally H-shaped configuration. The suture retainer 448 includes a rectangular base section 450 and a pair of arm sections 452 and 454. The arm sections 452 and 454 are connected with the base section 450 by a connector section 456. Although only the one side, which may be considered as the top side of the suture retainer 448 is illustrated in FIG. 16, the suture retainer has a generally rectangular configuration. The extent of the suture retainer 448 along the sections 442 and 444 of the suture 440 may be equal to the distance between longitudinal central axes of the sections of the suture.

**[0272]** The suture retainer 448 has a pair of recesses 460 and 462 in which the sections 442 and 444 of the suture 440 are received. An entrance 466 to the recess 460 (FIG. 17) is partially blocked by a nose or detent portion 468 of the arm section 452. When the suture section 442 is to be moved into the recess 460, the cylindrical outer side surface of the suture section 442 is pressed against a cam surface 472 on the nose portion 468 of the arm section 452. Force applied against the cam surface 472 resiliently deflects the arm section 452 away from the base section 450 from the position shown in solid lines in FIG. 17 to the position shown in dashed lines. As this occurs, the section 442 of the suture 440 moves into the recess 460. As the section 442 of the suture 440 moves into the recess 460, the arm section 452 springs back to the initial position shown in solid lines in FIG. 17 to block the entrance 446 to the recess 460. This results in the suture section 442 being retained in the recess 460.

**[0273]** The arm section 454 has the same construction as the arm section 452. Thus, the arm section 454 has a nose or detent portion 476 (FIG. 16) which is engaged by the suture section 444 to deflect the arm section 454 as the suture section moves into the recess 462. Once the suture section 444 has moved into the recess 462, the nose portion 476 on the arm section 454 blocks the entrance to the recess to retain the suture section 444 in the recess.

**[0274]** The suture 440 and suture retainer 448 are both formed of a biodegradable polymer. It is believed that it may be preferred to form the suture retainer 448 and suture 440 from an amorphous thermoplastic. The suture 440 and suture retainer 448 may be formed of the same material or different materials having similar chemical properties which are compatible. The suture 440 and suture retainer 448 may be formed of any of the materials previously mentioned herein or of other materials.

**[0275]** When the suture 440 and suture retainer 448 are to be utilized to secure human body tissue, the suture 440 is positioned relative to the body tissue, in a manner similar to that illustrated schematically in FIG. 1. The sections 442 and 444 of the suture 440 are then moved into the recesses 460 and 462 in the suture retainer 448. The nose portions 468 and 476 on the arm sections 452 and 454 are effective to retain the suture sections 442 and 444 in the recesses 460 and 462.

**[0276]** While the suture sections 442 and 444 are tensioned, the suture retainer 448 is moved along the suture 440 toward the body tissue. The nose portions 468 and 476 on the arm sections 452 and 454 maintain the suture sections 442 and 444 in the recesses 460 and 462 as the suture retainer 448 is moved along the suture 440 toward the body tissue. The suture retainer 448 is moved into engagement with either the body tissue, in the manner similar to that illustrated in FIG. 4, or into engagement with a force distribution member, in the manner similar to that illustrated in FIG. 5.

**[0277]** While a predetermined tension force is applied to the sections 442 and 444 of the suture 440 and while the suture retainer 448 is urged toward the body tissue with a predetermined force, the suture retainer 448 is bonded to the suture 440. This results in a

predetermined tension being maintained in the portion of the suture 440 connected with the body tissue and in the transmission of a predetermined force from the suture retainer 448 to the body tissue.

**[0278]** To bond the suture 440 to the suture retainer 448, an anvil or support portion 480 is pressed against the base section 450 of the suture retainer 448. A horn or acoustic tool 482 is pressed against the arm sections 452 and 454 of the suture retainer 448. The arm sections 452 and 454 of the suture retainer 448 have protuberances 486 and 488 which extend toward the horn 482.

**[0279]** The suture retainer 448 is clamped between the anvil 480 and horn 482. The force applied against the arm sections 452 and 454 by the horn 482 resiliently deflects the arm sections toward the base section 450 of the suture retainer 448. This results in the nose portions 468 and 476 on the arm sections 452 and 454 moving into engagement with the base section 450. Protuberances 486 and 488 on the arm sections 452 and 454 enable the horn 482 to deflect the arm sections through a sufficient distance to enable the arm sections to engage the base section 450.

**[0280]** Once the suture retainer 448 has been securely clamped between the anvil 480 and horn 482, ultrasonic vibratory energy is transmitted from the horn 482 to the suture retainer 448. The ultrasonic vibratory energy transmitted from the horn 482 to the suture retainer 448 is at a frequency of between 20 kilohertz and 70 kilohertz. It is believed that it may be preferred to apply ultrasonic vibratory energy at a frequency of approximately 70 kilohertz or more to the suture retainer 448.

**[0281]** The ultrasonic vibratory energy transmitted from the horn 482 to the suture retainer 448 is effective to heat the material of the suture retainer. The heat tends to be concentrated at the joints between the arm sections 452 and 454 and the base section 450. In addition, the heat tends to be concentrated at the joints between the suture sections 442 and 444 and the suture retainer 448.

**[0282]** The material of the suture retainer 448 is heated into a transition temperature range for the material. As the material of the suture retainer 448 is heated into the transition temperature range, the material of the suture retainer softens and becomes pliable. However, the material of the suture retainer 448 does not melt and become a liquid.

**[0283]** The heat softened material of the suture retainer 448 is plastically deformed by the force applied against the suture retainer by the anvil 480 and horn 482. As the material of the suture retainer 448 is plastically deformed, the recesses 460 and 462 are collapsed. The material of the suture retainer 448 is firmly pressed against the suture 440.

**[0284]** Once the material of the suture retainer 448 adjacent to the sections 442 and 444 of the suture and adjacent to the nose portions 468 and 476 on the arm sections has been heated into a transition temperature range and plastically deformed, the application of ultrasonic vibratory energy is interrupted. Heating the material of the suture retainer 448 into its transition temperature range causes the material to lose its rigidity and soften. The heat softened material of the suture retainer 448 can be deformed by the clamping force applied by the anvil 480 and horn 482.

**[0285]** Although the application of ultrasonic vibratory energy to the suture retainer 448 is interrupted, the suture retainer continues to be clamped between the anvil 480 and horn 482. If desired, the clamping force applied against the suture retainer 448 by the anvil 480 and horn 482 could be increased as the application of ultrasonic vibratory energy to the suture retainer is interrupted.

**[0286]** As the material of the suture retainer cools, the arm sections 452 and 454 of the suture retainer are bonded to the base section 450 of the suture retainer. In addition, the arm sections 452 and 454, connector section 456 and base section 450 of the suture retainer 448 are bonded to the sections 442 and 444 of the suture 440. This results in the suture 440 and the suture retainer 448 being securely interconnected.

[0287] In the foregoing description, the suture retainer 448 has been heated under the influence of ultrasonic vibratory energy transmitted from the horn 482 to the suture retainer. It is contemplated that the suture retainer 448 could also be heated by the direct application of thermal energy to the suture retainer. For example, a heating element could be provided in the anvil 480 and/or the horn 482 to function as a heat source. Alternatively, a heating element could be moved into contact with the suture retainer 448.

[0288] The anvil 480 and horn 482 do not engage the suture 440. The anvil 480 and horn 482 engage only the suture retainer 448. This prevents excessive heating and deformation of the suture 440. There is no significant deformation of the suture 440 so that it maintains its strength.

#### **Embodiment of FIGS. 18-20**

[0289] In the embodiment of the invention illustrated in FIGS. 16 and 17, the sections 442 and 444 of the suture 440 are positioned in a pair of recesses 460 and 462 in the suture retainer 448. In the embodiment of the invention illustrated in FIGS. 18-20, a single section of a suture is positioned in a single recess in a suture retainer. Since the suture retainer of the embodiment of the invention illustrated in FIGS. 18-20 is generally similar to the suture retainers of the embodiments of the invention illustrated in FIGS. 1-17, similar terminology will be utilized to identify similar components. It should be understood that one or more of the features of the other embodiments of the invention disclosed herein could be utilized in association with the embodiment of the invention illustrated in FIGS. 18-20.

[0290] A tissue securing system 489 (FIG. 18) is used in a sterile, operating room environment and includes a suture 490 and a suture retainer 496. The suture 490 (FIG. 18) has a section 492 which is connected with human body tissue in a manner generally similar to the manner illustrated schematically in FIG. 4. The suture section 492 may be connected with a suture anchor disposed in engagement with one side of a layer of body tissue. Alternatively, the suture section 492 may be connected with a suture anchor which is embedded in body tissue. The suture 490 could be connected with a suture anchor having a construction generally similar

to the construction of the suture anchors disclosed in U.S. Patents Nos. 5,584,862; 5,549,631; and/or 5,527,343.

**[0291]** A one-piece suture retainer 496 includes main sections 498 and 500. The main sections 498 and 500 of the suture retainer 496 are interconnected by a hinge section 502. The suture retainer 496 is formed separately from the suture 490.

**[0292]** The main sections 498 and 500 and hinge section 502 of the suture retainer 496 are integrally formed as one piece. The suture 490 and suture retainer 496 are both formed of a biodegradable polymer. It is believed that it may be preferred to form the suture 490 and suture retainer 496 from the same amorphous thermoplastic material. However, the suture 490 and suture retainer 496 may be formed of different amorphous thermoplastic materials having similar chemical properties. The suture 490 and suture retainer 496 may be formed from any of the materials previously mentioned herein or other materials.

**[0293]** The main sections 498 and 500 of the suture retainer 496 are initially skewed at an angle of approximately 30° to each other. The main sections 498 and 500 cooperate with the hinge section 502 to define a generally V-shaped recess 506 (FIG. 19) in which the section 492 of the suture is received. If desired, the recess 506 could have a configuration which is different than the illustrated V-shaped configuration.

**[0294]** While a predetermined tension is maintained in the suture 490, the suture retainer 496 is moved along the suture into engagement with the body tissue, in a manner generally similar to the manner illustrated in FIG. 4 or into engagement with a force distribution member, in the manner generally similar to the manner illustrated in FIG. 5. While a predetermined force is being transmitted from the suture retainer 496 to the body tissue and while the suture 490 is being tensioned with a predetermined force, the suture 490 is bonded to the suture retainer 496 and the main sections 498 and 500 of the suture retainer 496 are bonded together.

**[0295]** To effect securing of the suture 490 by the suture retainer 496, an anvil 512 (FIG. 20) is moved into engagement with the main section 498 of the suture retainer 496. At the same

time, a horn or acoustic tool 514 is moved into engagement with the main section 500 of the suture retainer 496. The anvil 512 and horn 514 apply force against the suture retainer 496 to clamp the suture retainer against the suture 490.

**[0296]** As the anvil 512 and horn 514 are clamped against the suture retainer 496, the main sections 498 and 500 of the suture retainer are deflected from the linear configuration illustrated in FIG. 19 to the bent configuration illustrated in FIG. 20. The anvil 512 and horn 514 have a configuration which corresponds to the desired configuration of the suture retainer 496 when the suture retainer is clamped against the suture 490 by the anvil and horn.

**[0297]** The suture retainer 496 is heated to effect a bonding between the main sections 498 and 500 of the suture retainer and to effect a securing of the suture 490 between the main sections 498 and 500 and the hinge section 502 of the suture retainer. To effect this, ultrasonic vibratory energy is transmitted from the horn 514 to the suture retainer 496. The ultrasonic vibratory energy transmitted from the horn 514 to the suture retainer 496 has a frequency of between 20 kilohertz and 70 kilohertz. It is believed that it may be preferred to transmit ultrasonic vibratory energy having a frequency of 70 kilohertz or more from the horn 514 to the suture retainer 496.

**[0298]** The ultrasonic vibratory energy transmitted from the horn 514 to the suture retainer 496 heats the material of the suture retainer. The heat tends to be concentrated at the joints between the main section 498 and 500 of the suture retainer and at the joints between the suture 490 and the main sections 498 and 500 and the hinge section 502 of the suture retainer. The material of the suture retainer 496 is heated into a transition temperature range for the material.

**[0299]** When the material adjacent to the main sections 498 and 500 of the suture retainer 496 and adjacent to the joint between the suture 490 and the suture retainer 496 has been heated into a transition temperature range, the application of ultrasonic vibratory energy to the suture retainer 496 is interrupted. Although the application of ultrasonic vibratory energy from the horn 514 to the suture retainer 496 is interrupted, the suture retainer continues to be clamped between

the anvil 512 and the horn 514. If desired, the force applied against the suture retainer 496 by the anvil 512 and horn 514 could be increased simultaneously with interruption of ultrasonic vibratory energy to the suture retainer 496.

**[0300]** As the material of the suture retainer 496 is heated into its transition temperature range, the material softens and loses its rigidity. Although the material of the suture retainer 496 softens as the material is heated into its transition temperature range, the material does not melt and become liquid. As the material of the suture retainer 496 softens, the force applied against the suture retainer 496 by the anvil 512 and horn 514 plastically deforms the suture retainer from the configuration illustrated in FIG. 19 to the configuration illustrated in FIG. 20.

**[0301]** As the material of the suture retainer 496 cools, a bond is formed between the main sections 498 and 500 of the suture retainer. In addition, the main sections 498 and 500 and the hinge section 502 of the suture retainer 496 are bonded to the suture 490. This results in the suture retainer 496 having a firm grip on the suture 490. The firm grip of the suture retainer 496 on the suture 490 enables a predetermined tension force to be transmitted through the suture 490 to the body tissue and enables a predetermined force to be transmitted from the suture retainer 496 to the body tissue.

**[0302]** The anvil 512 and horn 514 do not engage the suture 490. The anvil 512 and horn 514 engage only the suture retainer 496. This prevents excessive heating and deformation of the suture 490. The suture retainer 496 is bonded to the suture 490 without significant deformation of the suture.

**[0303]** In the embodiment of the invention illustrated in FIGS. 18-20, a single section 492 of the suture 490 is engaged by the suture retainer 496. However, a plurality of sections of suture could be gripped by the suture retainer 496. Thus, a pair of suture sections, corresponding to the suture sections 182 and 184 of FIG. 5, could be positioned in the recess 506 (FIG. 19) in the suture retainer 496 and gripped by the suture retainer. If desired, a force distribution member corresponding to the force distribution member 194 of FIG. 5 could be provided between the suture retainer 496 and the body tissue.

## **Embodiment of FIG. 21**

**[0304]** In the embodiment of the invention illustrated in FIGS. 18-20, the suture retainer 496 includes a pair of main sections 498 and 500 which are interconnected by a flexible hinge section 502 and which define a recess 506 in which the suture 490 is received. In the embodiment of the invention illustrated in FIG. 21, one section of a suture retainer cooperates with another section of the suture retainer to define a recess in which a suture is received. Since the embodiment of the invention illustrated in FIG. 21 is generally similar to the embodiment of the invention illustrated in FIGS. 1-20, similar terminology will be utilized to identify similar components. It should be understood that one or more of the features of the other embodiments of the invention illustrated herein could be used with the embodiment of the invention illustrated in FIG. 21.

**[0305]** A tissue securing system 518 is used in a sterile, operating room environment and includes a suture 520 and a suture retainer 528. The suture 520 (FIG. 21) includes a section 522 which is connected with body tissue. The section 522 of the suture 520 may be connected with body tissue in the manner illustrated schematically in FIG. 4. However, it should be understood that the suture 520 could be connected with body tissue in a different manner if desired.

**[0306]** The suture retainer 528 is formed separately from the suture 520 and encloses a portion of the suture. The suture retainer 528 has a rectangular configuration and includes a base section 530 and an arm section 532. The base and arm sections 530 and 532 of the suture retainer 528 are integrally formed as one piece. The arm section 532 cooperates with the base section 530 to define a generally U-shaped recess 534 in which the suture 520 is received.

**[0307]** The suture retainer 528 may have a configuration which is different than the configuration illustrated in FIG. 21. For example, the suture retainer 528 could have an ovoidal configuration rather than the illustrated rectangular configuration. Although the base section 530 has been illustrated as being substantially wider than the arm section 532, the base and arm sections could be of approximately the same width if desired. The base and arm sections 530 and 532 could have configuration similar to the configuration of the base section 450 and arm

section 452 of FIG. 16 if desired. If desired, the recess 534 could have a different configuration. For example, the recess 534 could have a configuration similar to the configuration of the recess 460 of FIG. 16.

**[0308]** The suture retainer 528 may be formed of any one of many different materials, including any of the materials previously mentioned herein. It may be preferred to form the suture retainer 528 of a biodegradable material. The suture 520 may be formed of the same biodegradable material as the suture retainer 528. It is believed that it may be preferred to form both the suture 520 and suture retainer 528 of an amorphous polymer, such as polyhydroxyalkanoate. Of course, the suture 520 and suture retainer may be formed of other materials if desired.

**[0309]** When the suture 520 and suture retainer 528 are to be utilized to secure body tissue, the suture 520 is positioned relative to body tissue by engagement with a suture anchor or other device. The suture 520 is then positioned in the recess 534 in the suture retainer 528. The suture 520 may be positioned in the recess 534 by moving the suture through an entrance to the recess. Alternatively, the suture retainer 528 could be moved relative to the suture.

**[0310]** Once the suture 520 has been positioned in the recess 534, a predetermined tension force is applied to the suture 520. The suture retainer 528 is moved along the suture toward the body tissue. The suture retainer is pressed against the body tissue in the manner illustrated schematically in FIG. 4 or pressed against a force distribution member in the manner illustrated schematically in FIG. 5. A predetermined force is transmitted from the suture retainer 528 to the body tissue while the predetermined tension is maintained in the suture 520.

**[0311]** To interconnect the suture 520 and suture retainer 528, the suture retainer is clamped between a horn and anvil of an ultrasonic energy application apparatus. Ultrasonic energy is then transmitted from the horn to the suture retainer 528 in the manner previously described in conjunction with the embodiments of the invention illustrated in FIGS. 1-20.

**[0312]** The clamping force applied against the suture retainer 528 by the horn and anvil deflects the arm section 532 of the suture retainer toward the base section 530 of the suture retainer. The arm section moves into engagement with the base section 530 of the suture retainer 528 and firmly grips the suture 520 under the influence of the clamping force applied by the anvil and horn.

**[0313]** Ultrasonic energy at a frequency of between 20 kilohertz and 70 kilohertz is then applied to the suture retainer 528 by the horn. The ultrasonic vibratory energy heats the material of the suture retainer 528 into its transition temperature range. As the material of the suture retainer 528 is heated into the transition temperature range, the material of the suture retainer softens and loses its rigidity. As this occurs, the softened material of the suture retainer 528 is plastically deformed by the clamping force applied against the suture retainer by the anvil and horn.

**[0314]** The transmission of ultrasonic vibratory energy to the suture retainer 520 is then interrupted. However, the clamping force against the suture retainer is maintained and may even be increased.

**[0315]** As the material of the suture retainer 528 cools, the suture retainer 528 is securely connected to the suture 520. Thus, the arm section 532 is bonded to the base section 530 of the suture retainer. Both the base section 530 and the arm section 532 are bonded to the suture 520. This results in the suture retainer 528 having a firm grip on the suture 520 to maintain the tension in the suture and the transmission of force from the suture retainer to body tissue.

## **Embodiment of FIG. 22**

**[0316]** In the embodiment of the invention illustrated in FIG. 21, the arm section 532 is generally straight and cooperates with the base section 530 to form a recess 534. In the embodiment of the invention illustrated in FIG. 22, the suture retainer has an arcuate arm section which cooperates with a base section to form a recess which receives a suture. Since the embodiment of the invention illustrated in FIG. 22 is generally similar to the embodiments of the

invention illustrated in FIGS. 1-21, similar terminology will be utilized to designate similar components. It should be understood that one or more of the features of the other embodiments of the invention disclosed herein could be utilized in conjunction with the embodiment of the invention illustrated in FIG. 22.

**[0317]** A suture 540 is connected with body tissue in the manner illustrated schematically in FIG. 4. A suture retainer 542 at least partially encloses the suture 540. The suture retainer 542 is integrally formed as one piece which is separate from the suture 540.

**[0318]** The suture retainer 542 includes a base section 544 and an arm section 546. The base section 544 and arm section 546 of the suture retainer are integrally formed as one piece. The suture retainer 542 has the same generally rectangular configuration as the suture retainer 528 of FIG. 21. However, the suture retainer 542 could have a different configuration if desired.

**[0319]** The suture retainer 542 may be formed of a biodegradable polymeric material. It is believed that it may be preferred to form both the suture 540 and the suture retainer 542 from the same biodegradable polymeric material. The suture 540 and suture anchor may be formed from an amorphous thermoset polymer. If desired, the suture retainer 542 and suture 540 could be formed of different polymeric materials which are compatible with each other. The suture 540 and suture retainer 542 could be formed from many different materials, including any of the materials mentioned herein.

**[0320]** The arm section 546 of the suture retainer 542 cooperates with the base section 544 of the suture retainer to define a recess 550 which receives a portion of the suture 540. The arm section 546 has a nose portion 554 which partially blocks an entrance 556 to the recess 550. The nose portion 554 on the arm section 546 is effective to retain the suture 540 in the recess 550.

**[0321]** When the suture 540 and suture retainer 542 are to be utilized to secure body tissue, the suture 540 is positioned relative to the body tissue in a manner similar to that illustrated in FIG. 4. Of course, the suture 540 could be connected with the body tissue in a

different manner if desired. For example, the suture 540 could be connected with a suture anchor which is embedded in the body tissue.

[0322] Once the suture 540 has been positioned relative to the body tissue, the suture is tensioned and positioned in the recess 550 in the suture retainer 542. To position the suture 540 in the recess 550, the suture can be moved relative to the recess or the recess can be moved relative to the suture.

[0323] As the suture 540 moves into the recess 556, the a cylindrical outer side surface of the suture applies force against a cam surface 558 on the nose portion 554 of the arm section 546. The force applied against the cam surface 558 deflects the arm section 546 outward away from the base section 544 of the suture retainer 542 to open the entrance 556 to the recess 550. This enables the suture 540 to move into the recess 550.

[0324] After the suture 540 has moved into the recess 550, the arm section 546 springs back to its initial position, illustrated in FIG. 22. When this occurs, the nose portion 554 on the arm section 546 partially blocks the entrance 556 to the recess 550 to retain the suture 540 in the recess.

[0325] Once the suture 540 has been positioned in the recess 550, the suture 540 is tensioned with a predetermined force and the suture retainer 542 is moved along the suture toward the body tissue. The suture retainer 542 is moved into engagement with the body tissue in the manner illustrated in FIG. 4 or is moved into engagement with a force distribution member in the manner illustrated in FIG. 5. A predetermined force is transmitted from the suture retainer 542 to the body tissue while the predetermined tension is maintained in the suture 540. This results in layers of body tissue being pressed against each other.

[0326] The suture retainer 542 and suture 540 are then interconnected to maintain the predetermined tension in the portion of the suture 540 connected with the body tissue and to maintain the transmission of the predetermined force from the suture retainer to the body tissue. To interconnect the suture retainer 542 and suture 540, the suture retainer is clamped between an

anvil 562 and a horn 564 of an ultrasonic energy application apparatus. The clamping force applied against the suture retainer 542 by the anvil 562 and horn 564 resiliently deflects the arm section 546 so that the nose portion 554 of the arm section moves into engagement with the base section 544 of the suture retainer. In addition, the arm section 546 is firmly pressed against the suture 540.

[0327] While the clamping force is applied to the suture retainer 542 by the anvil 562 and horn 564, ultrasonic vibratory energy is transmitted from the horn to the suture retainer. The ultrasonic vibratory energy has a frequency of between 20 kilohertz and 70 kilohertz. It is believed that it may be preferred to utilize ultrasonic vibratory energy having a frequency of approximately 70 kilohertz or more.

[0328] The ultrasonic vibratory energy heats the material of the suture retainer into its transition range. The heat tends to be concentrated at the joint between the arm section 546 and the base section 544 of the suture retainer 542. In addition, the heat is concentrated at the joint between the suture 540 and the suture retainer 542.

[0329] Once the material of suture retainer 542 has been softened by being heated into its transition temperature range, the application of ultrasonic vibratory energy to the suture retainer is interrupted. Even though the application of ultrasonic vibratory energy to the suture retainer is interrupted, the clamping force applied against the suture retainer 542 by the anvil 562 and horn 564 is maintained or even increased.

[0330] As the material of the suture retainer 542 cools, a secure bond is formed between the arm section 546 and the base section 544 of the suture retainer. In addition, a secure bond is formed between the suture 540 and the base section 544 and arm section 546 of the suture retainer 542.

### **Embodiment of FIG. 23**

[0331] In the embodiments of the invention illustrated in FIGS. 1-22, various types of suture retainers for use in securing a suture relative to body tissue have been illustrated. The

embodiment of the invention illustrated in FIG. 23 is not limited to any particular suture retainer construction. However, similar terminology will be utilized in describing the components of the embodiment of the invention illustrated in FIG. 23 as were previously utilized in connection with the embodiments of the invention illustrated in FIGS. 1-22.

**[0332]** In the embodiment of the invention illustrated in FIG. 23, a relatively thick layer of tissue, designated by the numeral 570, is to be connected with a relatively thin layer of tissue, designated by the numeral 572. A tissue securing system 574 is utilized to interconnect the thick and thin layers of tissue. The tissue securing system 574 is located a precise distance from an end 578 of the thick layer 570 of tissue and an end 580 of the thin layer 572 of tissue.

**[0333]** In the illustrated embodiment of the invention, the tissue securing system 574 is located the same distance from the end 578 of the thick layer of tissue as in which the tissue fixation system is located from the end 580 of the thin layer of tissue. This results in the two layers of tissue growing together with a minimum of scarring. In addition, the tissue securing system 574 holds the thick layer 570 and the thin layer 572 of tissue against shifting relative to each other.

**[0334]** If a staple of loop-type suture was used to interconnect the thick layer 570 and thin layer 572 of tissue, a shifting could occur between the two layers of tissue. This shifting could occur inside of the loop formed by the suture or the staple. The shifting can result in extensive scarring and could result in a non-uniform repair of the tissue. The obtaining of a uniform repair of tissue is particularly important when interconnecting a conduit, such as a blood vessel, which has been severed. By using the tissue securing system 574, shifting movement can not occur between the thick layer 570 and thin layer 572 of tissue. This prevents one of the layers from being deflected into the path of flow of material, such as blood, through the conduit in a manner which restricts the conduit and subsequently results in a blockage.

**[0335]** The specific tissue securing system 574 illustrated in FIG. 23 includes a suture anchor 584 which is disposed in engagement with an outer side surface of the thin layer 572 of tissue. A suture 586 extends through both the thin layer 572 of tissue and the thick layer 570 of

tissue. The suture 586 is disposed the same distance from the end 578 of the thick layer 570 of tissue as it is located from the end 580 of the thin layer 572 of tissue. A suture retainer 590 is connected with a portion of the suture 586 opposite from the anchor 584. The suture retainer 590 may have any one of the constructions described herein or a different construction.

**[0336]** In accordance with a feature of the present invention, the suture retainer 590 is connected with the suture 586 by the application of ultrasonic vibratory energy to the suture retainer 590. The application of ultrasonic vibratory energy to the suture retainer 590 results in a rapid heating of the material of the suture anchor. The very short time which is required to heat the material of the suture retainer 590 by the application of ultrasonic vibratory energy enables the suture retainer to be heated into its transition temperature range and softened without detrimentally affecting the layers 570 and 572 of body tissue.

**[0337]** Although it is contemplated that the amount of heat which is required to heat material of the suture retainer 590 into the transition temperature range by the application of ultrasonic vibratory energy will vary depending upon the construction of the suture retainer 590, an ultrasonic vibratory energy application time of between 0.25 seconds and 1.0 seconds is required to connect any one of the suture retainers of FIGS. 1-22 with a suture. After the suture retainer 590 has been heated and the application of ultrasonic vibratory energy interrupted, the suture retainer is allowed to cool for approximately one second. Since the suture retainer 590 is heated into its transition temperature range for an extremely short period of time, the suture retainer can be heated to relatively high temperatures which would be detrimental to the layers 570 and 572 of the body tissue if the application of ultrasonic vibratory energy was maintained over an extended period of time.

**[0338]** In the embodiments of the invention illustrated in FIGS. 1, 4 and 23, the tissue securing systems are being utilized to interconnect layers of soft tissue disposed in juxtaposition with each other. However, it is contemplated that the tissue securing system could be utilized to interconnect body tissues having different characteristics. For example, the tissue securing system could be utilized to connect soft tissue, such as a tendon, or ligament, with bone. If the tissue securing system was utilized to connect soft tissue with bone, the suture anchor would

engage the bone in a manner similar to that disclosed in U.S. Patent No. 5,403,348 and/or 5,534,012. The suture would then extend from the anchor positioned in the bone into engagement with the soft body tissue. The suture could be wrapped around the soft body tissue or, alternatively, could extend through the soft body tissue. A suture retainer having any of the constructions illustrated in FIGS. 1-22 could be connected with one or two sections of the suture to hold the soft body tissue in place relative to the bone.

[0339] Although it is preferred to connect the suture retainers illustrated in FIGS. 1-22 with a suture, the suture retainers could be connected with other force transmitting members or directly with body tissue if desired. For example, any one of the suture retainers of FIGS. 1-22 could be connected with a K-wire or a rigid force transmitting member such as a rod or externally threaded stud. Alternatively, the suture retainer could be connected directly to body tissue, such as a ligament or tendon.

[0340] In the embodiments of the invention illustrated in FIGS. 1-22, the suture retainers have been connected with sutures formed of polymeric material. However, the sutures could be formed of metal if desired. Thus, the suture retainers illustrated in FIGS. 1-22 could be connected with any desired type of member which transmits force, including body tissue.

[0341] It is contemplated that the suture retainers illustrated in FIGS. 1-22 will be utilized in an operating room environment. The suture retainers may be positioned within and fully enclosed by a patient's body. Alternatively, the suture retainers may be partially disposed outside of the patient's body.

#### **Embodiment of FIG. 24**

[0342] It is contemplated that the suture retainers of FIGS. 1-23 may be heated by the application of ultrasonic vibratory energy. The ultrasonic vibratory energy may be applied in many different ways. One known apparatus for applying the ultrasonic vibratory energy to any one of the suture retainers of FIGS. 1-23 is illustrated schematically in FIG. 24.

[0343] An ultrasonic vibratory energy application apparatus 600 includes a pair of compression members 602 and 604 which are interconnected at a pivot connection 606. An anvil or support member 610 is mounted on one end portion of the member 602. A horn or ultrasonic energy application member 612 is mounted on one end portion of the member 604

[0344] Sections 614 and 616 of a suture retainer are disposed in engagement with the anvil 610 and horn 612. The sections 614 and 616 of the suture retainer may have the same construction as the sections 222 and 224 of the suture retainer 220 of FIG. 6. When handle end portions 620 and 622 of the members 602 and 604 are moved together, the anvils 610 and horn 612 press the sections 614 and 616 of the suture retainer against sections 626 and 628 of a suture.

[0345] Referring to FIG. 25A, a generator 630 is connected with a standard electrical power supply (120-240 volts). The generator 630 converts the standard electrical power supply from 50/60 hertz to an ultrasonic frequency, that is a frequency greater than 20 kilohertz. The high frequency electrical energy is conducted through a cable 632 to the member 604.

[0346] Suitable electrically insulated conductors in the member 604 conduct the high frequency electrical energy through a transducer (not shown) connected with the horn. The transducer changes the electrical energy into longitudinal ultrasonic signal resulting in a low amplitude mechanical vibrations. These vibrations may be transmitted to a booster to increase or decrease the amplitude of the vibrations. The vibrations are then transmitted to the horn 612.

[0347] The horn 612 has a longitudinal axis 634 along which the longitudinal ultrasonic signal is propagated. The ultrasonic energy is directed through the horn 612 to end portion 636 of the horn 612. As a result the vibrational energy at the end portion 636 of the horn 612 is greater than the vibrational energy at a side portion 638, wherein the side portion 638 is substantially orthogonal to the end portion 636 of the horn 612.

[0348] In an embodiment, the horn 612 is affixed to member 604, such that the end portion 636 of the horn 612 presses the sections 614 and 616 of the suture retainer against sections 626 and 628 of a suture when handle end portions 620 and 622 of the members 602 and

604 are moved together. The vibrational energy is transmitted through the end portion 636 of the horn 612 to the suture retainer sections 614 and 616. Alternatively, an end deflector is interposed between the end portion 636 of the horn 612 and the suture retainer. The end deflector transfers the energy from the horn 612 to the suture retainer.

**[0349]** In an embodiment, the horn 612 is affixed to member 604, such that the side portion 638 of the horn 612 presses the sections 614 and 616 of the suture retainer against sections 626 and 628 of a suture when handle end portions 620 and 622 of the members 602 and 604 are moved together. The vibrational energy is transmitted through the side portion 638 of the horn 612 to the suture retainer sections 614 and 616. Alternatively, an end deflector is interposed between the side portion 638 of the horn 612 and the suture retainer. The end deflector transfers the energy from the horn 612 to the suture retainer.

**[0350]** Alternatively, the generator 630 converts the energy of the standard electrical power supply to an ultrasonic frequency. Suitable electrically insulated conductors in the member 604 conduct the high frequency electrical energy through a transducer (not shown) connected with the horn 612. The transducer changes the electrical energy into torsional ultrasonic signal resulting in low amplitude mechanical vibrations.

**[0351]** The horn 612 is a cylindrical member affixed to member 604, such that the side portion 638 of the horn 612 presses the sections 614 and 616 of the suture retainer against sections 626 and 628 of a suture when handle end portions 620 and 622 of the members 602 and 604 are moved together. The torsional ultrasonic signal propagates about the circumference of the horn 612, wherein the vibrational energy from the torsional ultrasonic signal is transmitted about the side portion 638 of the horn 612 to the suture retainer sections 614 and 616. Alternatively, an end deflector is interposed between the side portion 638 of the horn 612 and the suture retainer. The end deflector transfers the energy from the horn 612 to the suture retainer.

**[0352]** It is also contemplated that the above described horn 612 can have different configurations, including, but not limited to, a hollow cylinder, wherein the torsional ultrasonic

signal propagates about the circumference of the hollow cylinder, and a flattened side portion configured for receiving at least one of the suture retainer sections 614 and 616 thereon.

**[0353]** In an embodiment, the ultrasonic vibratory energy application apparatus 600 includes a bias member, biasing the anvils 610 and horn 612 in a closed position. The suture retainer is loaded in the apparatus by moving the handle end portions 620 and 622 of the members 602 and 604 to separate the anvil 610 and horn 612. The suture retainer sections 614 and 616 are then disposed in engagement with the anvil 610 and horn 612. The suture retainer can be loaded in the apparatus either intra-corporally or extra-corporally.

**[0354]** When a suture and suture retainer are to be used to secure the human body tissue, the suture is positioned relative to the body tissue. The suture sections 626 and 628 are formed separately from the suture retainer first and second sections 614 and 616. The suture is positioned relative to human body tissue with the suture sections 626 and 628 extending away from an outer side surface of the body tissue. The suture may be connected with the body tissue in the same manner as illustrated schematically in FIG. 1 if desired. A predetermined tension force is then applied to the suture sections 626 and 628.

**[0355]** The suture is positioned in the suture retainer by moving the handle end portions 620 and 622 of the members 602 and 604 of the vibratory energy application apparatus 600 to separate the anvil 610 and horn 612. The suture sections 626 and 628 are then positioned in relation to the suture retainer sections 614 and 616. The bias member moves the anvils 610 and horn 612 together, pressing suture retainer sections 614 and 616 against suture sections 626 and 628. The bias member compresses the suture retainer sections 614 and 616 together with a compressive force between about 1 lb. to 20 lbs. The suture retainer sections 612 and 614 are bonded together and to the suture sections 626 and 628 using ultrasonic vibratory energy. The suture can be positioned in the suture retainer either intra-corporally or extra-corporally.

## **Embodiment of FIG. 25**

[0356] In the embodiment of the invention illustrated in FIG. 24, the horn and anvil are disposed on a pair of compression members 602 and 604 which are pivotally interconnected. In the embodiment of the invention illustrated in FIG. 25, the horn and anvil of an ultrasonic energy application apparatus are movable relative to each other along a linear path.

[0357] The ultrasonic energy application apparatus 640 of FIG. 25 includes a handle 642. A first compression member including a horn 644 is connected with the handle 642. A second compression member including an anvil 646 is integrally formed as one piece with a member 648 which is movable along a linear path relative to the handle 642. An actuator member 650 is connected with the member 648 and is movable toward the left (as viewed in FIG. 25) to move the anvil 646 toward the horn 644.

[0358] Sections 660 and 662 of a suture are disposed between the sections 656 and 658 of the suture retainer. The suture retainer may have a construction similar to the construction of the suture retainer illustrated in FIG. 6.

[0359] Referring also to FIG. 25A, a generator 666 is connected with the handle 642 by a cable 668. The cable 668 connects the generator 666 with a transducer which changes high frequency electrical energy conducted from the generator 666 to a longitudinal ultrasonic signal resulting in low amplitude mechanical vibrations. These vibrations are transmitted to a booster. The vibrations are then transmitted to the horn. The horn applies the vibrations to the sections 658 of the suture retainer.

[0360] The horn 644 has a longitudinal axis 670 along which the ultrasonic signal is propagated. The ultrasonic signal is directed through the horn 644 to end portion 672 of the horn 644. As a result the vibrational energy at the end portion 672 of the horn 644 is greater than the vibrational energy at a side portion 674, wherein the side portion 674 is substantially orthogonal to the end portion 672 of the horn 644.

**[0361]** In an embodiment, the horn 644 is affixed to the handle 642, such that the end portion 670 of the horn 644 presses the sections 656 and 658 of the suture retainer against sections 660 and 662 of a suture when the actuator member 650 and member 648 are moved toward the left (as viewed in FIG. 25). The vibrational energy is transmitted through the end portion 670 of the horn 644 to the suture retainer sections 656 and 658. Alternatively, an end deflector is interposed between the end portion 670 of the horn 644 and the suture retainer. The end deflector transfers the energy from the horn 644 to the suture retainer.

**[0362]** In an embodiment, the horn 644 is affixed to the handle 642, such that the side portion 672 of the horn 644 presses the sections 656 and 658 of the suture retainer against sections 660 and 662 of a suture when the actuator member 650 and member 648 are moved toward the right (as viewed in FIG. 25). The vibrational energy is transmitted through the side portion 672 of the horn 644 to the suture retainer sections 656 and 658. Alternatively, an end deflector is interposed between the side portion 672 of the horn 644 and the suture retainer. The end deflector transfers the energy from the horn 644 to the suture retainer.

**[0363]** Alternatively, the generator 666 converts the energy of the standard electrical power supply to an ultrasonic frequency. Suitable electrically insulated conductors in the conduct the high frequency electrical energy through a transducer (not shown) connected with the horn 644. The transducer changes the electrical energy into torsional ultrasonic signal resulting in low amplitude mechanical vibrations.

**[0364]** The horn 644 is a cylindrical member affixed to the handle 642, such that the side portion 672 of the horn 644 presses the sections 656 and 658 of the suture retainer against sections 660 and 662 of a suture when the actuator member 650 and member 648 are moved toward the right (as viewed in FIG. 25). The torsional ultrasonic signal propagates about the circumference of the horn 644, wherein the vibrational energy from the torsional ultrasonic signal is transmitted through the side portion 672 of the horn 644 to the suture retainer sections 656 and 658. Alternatively, an end deflector is interposed between the side portion 672 of the horn 644 and the suture retainer. The end deflector transfers the energy from the horn 644 to the suture retainer.

**[0365]** It is also contemplated that the above described horn 644 can have different configurations, including, but not limited to, a hollow cylinder, wherein the torsional ultrasonic signal propagates about the circumference of the hollow cylinder, and a flattened side portion configured for receiving at least one of the suture retainer sections 614 and 616 thereon.

**[0366]** In an embodiment, the actuator member 650 can include a bias member, biasing the anvils 646 and horn 644 in a closed position. The suture retainer is loaded in the apparatus by moving the actuator member 650 to separate the anvil 646 and horn 644. The suture retainer is then positioned between the anvil 646 and horn 644. The suture retainer can be loaded in the apparatus either intra-corporally or extra-corporally.

**[0367]** When a suture and suture retainer are to be used to secure the human body tissue, the suture is positioned relative to the body tissue. The suture is formed separately from the suture retainer. The suture is positioned relative to human body tissue with the suture extending away from an outer side surface of the body tissue. The suture may be connected with the body tissue in the same manner as illustrated schematically in FIG. 1 if desired. A predetermined tension force is then applied to the suture.

**[0368]** The suture is positioned in the suture retainer by moving the actuator member 650 to separate the anvil 646 and horn 644. The suture is then positioned in relation to the suture retainer. The bias member moves the anvils 646 and horn 644 together, pressing suture retainer against suture, securing the suture retainer about the suture. The bias member compresses the suture retainer with a compressive force between about 1 lb. to 20 lbs. The suture can be positioned in the suture retainer either intra-corporally or extra-corporally.

**[0369]** It should be understood that the ultrasonic energy application apparatus of FIGS. 24 and 25 could have any desired construction. It is contemplated that ultrasonic energy application apparatus which is commercially available from Dukane Corporation may be utilized. Of course, ultrasonic energy application apparatus which is commercially available from other sources may be used if desired. It should be understood that the suture retainers of

FIGS. 1-23 may be utilized in association with any desired ultrasonic energy application apparatus.

#### **Embodiment of FIGS. 26-28**

**[0370]** In the embodiments of the invention illustrated in FIGS. 1-22, a suture retainer has been utilized to interconnect sections of a suture. In the embodiment of the invention illustrated in FIGS. 26 through 28, the sections of the suture are directly connected to each other. Since the embodiment of the invention illustrated in FIGS. 26-28 is generally similar to the embodiments of the invention illustrated in FIGS. 1-22, similar terminology will be utilized to identify similar components. It should be understood that one or more of the features of other embodiments of the invention illustrated herein could be used with the embodiment of the invention illustrated in FIGS. 26-28.

**[0371]** A tissue securing system 680 (FIG. 26) includes a suture 682. The suture 682 includes left and right sections 684 and 686 which are interconnected without using a suture retainer. The two sections 684 and 686 may be knotted together and then interconnected. Alternatively, the two suture sections may just be interconnected, without knotting in the manner illustrated in FIGS. 27 and 28.

**[0372]** The tissue securing system 680 secures upper and lower layers 690 and 692 of soft, human body tissue in linear apposition with each other. Thus, the two layers 690 and 692 of human body tissue are approximated and held against movement relative to each other by a suture 682. Although the two layers 690 and 692 of human body tissue have been schematically illustrated in FIG. 26 as being spaced apart from each other, they are held in a side-by-side relationship with each other and pressed together by tightening the tissue securing system 680. Pressing the two layers 690 and 692 together with the tissue securing system 680 promotes healing of the tissue.

**[0373]** Although the tissue securing system 680 has been illustrated in FIG. 26 as being used to hold layers of soft tissue in linear apposition with each other, it is contemplated that the

tissue securing system may be used in many different locations in a patient's body to secure tissue. For example, the tissue securing system 680 could be utilized to secure soft tissue such as a ligament or tendon against movement relative to a bone. Alternatively, the tissue securing system 680 could be utilized to interconnect portions of a flexible conduit, such as a blood vessel or intestine. It should be understood that the tissue securing system 680 may be used with either hard body tissue or soft body tissue or both hard and soft body tissue.

**[0374]** A force distribution member 694 is disposed between the two sections 684 and 686 of the suture 682. When the suture 682 is tensioned, the force distribution member 694 distributes the force over a relatively large area of the upper layer 690 of body tissue. Although only the force distribution member 694 is illustrated in FIG. 26 in association with the upper layer 690 of body tissue, a similar force distribution member could be provided in association with the lower layer 692 of body tissue if desired.

**[0375]** In accordance with a feature of this embodiment of the invention, the sections 684 and 686 of the suture 682 are interconnected without using a suture retainer similar to the suture retainers illustrated in FIGS. 1-22 herein. In the embodiment of the invention illustrated in FIGS. 26-28, the two sections 684 and 686 of the suture 682 are heated, flattened, and bonded together. Heating the suture sections 684 and 686 softens the material of the suture sections and allow them to be plastically deformed from a cylindrical configuration to a flat, generally planar configuration. Flattening the cylindrical sections 684 and 686 of the suture 682 increases the area at which the suture sections can be interconnected and thereby increases the strength of the connection between the suture sections.

**[0376]** The suture 682 may be formed of many different materials, including the materials previously mentioned herein. The suture 682 may be formed of either a biodegradable or a non-biodegradable material. It is believed that it will be preferred to form the suture 682 of a biodegradable material. It may be preferred to form the suture 682 of a biodegradable amorphous polymer. For example, the suture 682 could be formed of polyhydroxyalkanoate. Of course, the suture 682 could be formed of other materials if desired. Additionally, the suture 682 may be a monofilament or multifilament, being formed of a plurality of interconnected filaments.

**[0377]** When the suture 682 is to be connected with the layers 690 and 692 of body tissue, the suture is positioned as illustrated schematically in FIG. 26. The sections 684 and 686 of the suture 682 are tensioned with a predetermined force. While the sections 684 and 686 of the suture are being tensioned, the force distribution member 694 is pressed against the upper layer 690 of body tissue. This results in the upper and lower layers 690 and 692 of the body tissue being compressed together with a predetermined force.

**[0378]** Once the layers 690 and 692 have been pressed together with a predetermined force by tensioning the sections 684 and 686 of the suture 682 and pressing the force distribution member 694 against the body tissue, the sections of the suture are interconnected. To interconnect the sections 684 and 686 of the suture 682, the two sections are pulled tight across the force distribution member and disposed in an overlapping relationship. An anvil 700 is positioned on one side of the two sections 684 and 686 of the suture 682. A horn 702 is positioned on the opposite side of the sections 684 and 686 of the suture 682. The anvil 700 and horn 702 are pressed against the opposite sides of the suture 682 with a predetermined force.

**[0379]** The suture sections 684 and 686 are stacked in a side-by-side relationship between the anvil 700 and horn 702. The anvil 700 engages one suture section and the horn 702 engages the other suture section. Thus, the anvil 700 may engage the suture section 684 and the horn 702 may engage the suture section 686.

**[0380]** While the sections 684 and 686 of the suture 682 are clamped between the anvil 700 and horn 702, ultrasonic vibratory energy is transmitted from the horn 702 to the sections 684 and 686 of the suture. At this time, the suture sections are tensioned with a predetermined force. The ultrasonic vibratory energy is at a frequency of between 20 kilohertz and 70 kilohertz. It is believed that it may be preferred to transmit ultrasonic vibratory energy to the sections of the suture 682 at a frequency of 70 kilohertz or more.

**[0381]** The ultrasonic vibratory energy transmitted from the horn 702 to the suture 682 is effective to heat the material of the suture into its transition temperature range. As the material of the suture 682 is heated into its transition temperature range, the material loses its rigidity and

softens. However, the material of the suture 682 does not melt and become a liquid as it is heated into the transition temperature range.

[0382] The heated and softened material of the sections 684 and 686 of the suture 682 are flattened from the cylindrical configuration of FIG. 27 to form thin layers which are disposed in a side-by-side relationship and have a generally plate-like configuration which is illustrated schematically in FIG. 28. Thus, the section 684 of the suture is flattened to form a layer 706 having an upper major side surface 708 which extends parallel to a lower major side surface 710 of the layer 706. Similarly, the section 686 of the suture 682 is flattened to form a layer 714 having a flat upper major side surface 716 which extends parallel to a lower major side surface 718 of the layer 714.

[0383] As the section 684 of the suture 682 is flattened, it is extended sideways in opposite directions along a path which extends perpendicular to a central axis 722 (FIG. 28) of the suture section 684. Similarly, as the section 686 of the suture 682 is flattened, it is extended sideways in opposite directions along a path which extends perpendicular to a central axis 724 of the suture section 686. Although the flattened suture sections 684 and 686 have been illustrated as having planar major side surfaces 708, 710, 716 and 718, the suture sections could be flattened in such a manner as to have arcuately curving major side surfaces. For example, the major side surfaces 708, 710, 716 and 718 of the flattened suture sections 684 and 686 could curve upward (as viewed in FIG. 27) away from the body tissue 690.

[0384] The side surfaces 708, 710, 716 and 718 all have a relatively large area. The area of each unit of length as measured along a longitudinal central axes 722 and 724 of the suture sections at the side surfaces 708, 710, 716 and 718, is greater than the corresponding area of a unit of length of the section of the suture having the cylindrical configuration illustrated in FIG. 27.

[0385] Thus, a one-inch length of a cylindrical portion of the suture 682 has a circumferential area of  $\pi$  (3.1416) times the diameter of the cylindrical section 684 of the suture 682. A one inch length, as measured along a longitudinal central axis 722 of the suture section

684, of the upper side surface 708 of the layer 706 has an area which is greater than  $\pi$  (3.1416) times the diameter of the cylindrical portion of the suture 682. Similarly, a unit of length of the upper major side surface 716 of the layer 714 is greater than the area of a unit of length of the cylindrical portion of the suture 682.

[0386] When the sections 684 and 686 of the suture 682 have been heated and flattened from the cylindrical configuration of FIG. 27 to the plastically deformed and flattened configuration of FIG. 28 by the anvil 700 and horn 702, the application of ultrasonic vibratory energy to the layers 706 and 708 by the horn 702 is interrupted. As the material of the layers 706 and 714 cools, a secure bond is formed between the layers 706 and 714 throughout the extent of the lower major side surface 710 of the upper layer 706 and the upper major side surface 716 of the lower layer 714. The relatively large area of the bond between the two layers 706 and 714 provides a strong interconnection between the two suture sections 684 and 686.

[0387] In the foregoing description, the sections 684 and 686 were heated, under the influence of ultrasonic vibratory energy transmitted from the horn 702, and flattened to have surface areas which are greater than the surface area of a corresponding length of a cylindrical portion of the suture 682. However, it is contemplated that the sections 684 and 686 of the suture 682 could be flattened to a lesser extent. If this was done, the area of one of the major side surfaces, for example the lower major side surface 710 of the layer 706, might not be as great as the area of a corresponding length of a cylindrical portion of the suture 682. Thus, the sections 684 and 686 of the suture 682 may be flattened and extended sideways to a greater or lesser extent. Even a relatively small extent of flattening of the sections 684 and 686 of the suture 682 will result in an increase in the area at which the two sections of the suture are bonded together. This is because the circumferential extent of a bond formed between a pair of cylindrical surfaces disposed in tangential engagement is relatively small. The extent of the bond between the surfaces 710 and 716 is relatively large even though the surfaces have a smaller extent than illustrated in FIG. 28.

### **Embodiment of Figures 30A-30B**

[0388] Referring to FIGS. 30A-30B, the suture retainer 740 includes a first section 742 and a second section 744 formed separately from each other. However, it is contemplated that the two sections 742 and 744 could be interconnected by a flexible connector section. The flexible connector section may be formed as one piece with the first section 742 and the second section 744 of the suture retainer 740.

[0389] The first section 742 of the suture retainer 740 includes a top surface 746 and a bottom surface 748. The bottom surface 748 includes a pair of parallel channels 750 and 752 extending along the length of the bottom surface 748. The parallel channels 750 and 752 are divided by a center extension 754 extending along the length of the bottom surface 748.

[0390] The second section 744 of the suture retainer 740 includes a top surface 756 and a bottom surface 758, wherein the top surface 756 includes a center channel 760 configured for receiving the center extension 754 of the first section 742. The width of the second section 744 is less than the width of the first section 742, such that the second section 744 is positionable within the first section 742.

[0391] The end portion of the center extension 754 has a pointed configuration. Thus, the end portion of the center extension 754 terminates in a tip. Therefore, there is line contact between the end of the center extension 754 and the end of the center channel 760.

[0392] By forming the end portion of the center extension 754 with a pointed configuration, the end portion of the center extension 754 is effective to function as energy director for ultrasonic vibratory energy. The pointed end of the center extension 754 is effective to direct ultrasonic vibratory energy transmitted from the first section 742 of the suture retainer 740 to the end portion of the center extension 754 and center channel 760. The pointed configuration of the end portion of the center extension 754 concentrates the energy and facilitates melting of the material of the projections. To a lesser extent, the material of the second section 744 of the retainer 740 is melted adjacent to the bottom surfaces of the center

channel 760. This results in a secure bonding and interconnection between the first and second sections 742 and 744 of the retainer 740.

**[0393]** When a suture 762 and suture retainer 740 are to be used to secure human body tissue, the suture 762 is positioned relative to the body tissue. The suture includes ends 764 and 766 which are formed separately from the first and second sections 742 and 744 of the suture retainer 740. The suture 762 is positioned relative to human body tissue with the ends 764 and 766 extending away from an outer side surface of the body tissue. The suture 762 may be connected with the body tissue in the same manner as illustrated schematically in FIG. 1 if desired. A predetermined tension force is then applied to the ends 764 and 766 of the suture 762.

**[0394]** The two sections 742 and 744 of the suture retainer 740 are positioned in engagement with the suture ends 764 and 766, wherein the suture ends 764 and 766 are positioned one each in the parallel channels 750 and 752 of the first section 742 of the suture retainer 740. The second section 744 of the suture retainer 740 engages the first section 742 of the suture retainer 740 such that the center extension 754 is positioned within the center channel 760 and the suture ends 764 and 766 are interposed between the bottom surface 748 of the first section 742 and the top surface 756 of the second section 744 of the suture retainer 740. The suture retainer 740 is pressed against the body, resulting in the body tissue being pressed between the suture retainer 740 and the portion of the suture 762 connected with the body tissue. A force distribution member could be provided between the suture retainer 740 and body tissue if desired.

**[0395]** In order to bond the suture retainer sections 742 and 744 to each other and to the suture ends 764 and 766, ultrasonic vibratory energy is transmitted to the suture retainer 740. To effect the transmission of ultrasonic vibratory energy to the suture retainer sections 742 and 744, an anvil 768 is moved into engagement with the second section 744 of the suture retainer 740. A horn or acoustic tool 770 is moved into engagement with the first section 742 of the suture retainer 740. Alternatively, the anvil 768 can engage the first section 742 and the horn 770 can engage the second section 744. The anvil 768 and horn 770 are pressed against the suture

retainer sections 742 and 744 with a predetermined force to firmly press the sections 742 and 744 against the suture ends 764 and 766.

**[0396]** While the anvil 768 and horn 770 are being pressed against the suture retainer sections 742 and 744 with a predetermined force, ultrasonic vibrations are transmitted from the horn 770 to the suture retainer 740. The ultrasonic vibrations transmitted to the suture retainer 740 create frictional heat and cause portions of the material of the suture retainer 740 to be heated into the transition temperature range for the material. As the material of the suture retainer 740 is heated into its transition temperature range, the material loses some of its rigidity and softens. The material of the suture retainer 740 does not melt and become liquid. The heat in the suture retainer 740 will tend to be concentrated adjacent to the channels 750, 752, and 760 and the center extension 754.

**[0397]** As the material of the suture retainer 740 is heated and softened by the ultrasonic vibratory energy, the suture retainer sections 742 and 744 are pressed together by force applied by the anvil 768 and horn 770. As this occurs, the material of the suture retainer sections 742 and 744 is plastically deformed and pressed against the suture ends 764 and 766 at the channels 750 and 752 in the suture retainer 740. At the same time, at least portions of the bottom surface 748 of the first section 742 and the top surface 756 of the second section 744 of the suture retainer 740 will move into engagement with each other.

**[0398]** When this has occurred, the transmission of ultrasonic energy to the suture retainer 740 is interrupted. However, the force applied against the suture retainer sections 742 and 744 is maintained. It is believed that it may be desired to increase the force applied against the suture retainer sections 742 and 744 by the anvil 768 and horn 770 as the application of ultrasonic vibratory energy to the suture retainer 740 is interrupted. For example, the force applied to the suture retainer 740 can be substantially between 1 to 20 lbs.

**[0399]** While the clamping force applied by the anvil 768 and horn 770 is maintained, the first and second sections 742 and 744 of the suture retainer 740 bond to each other. In addition, the first and second sections 742 and 744 of the suture retainer 740 are compressed about the

suture ends 764 and 766. This results in the suture 762 being firmly gripped by the suture retainer sections 742 and 744. The suture retainer sections 742 and 744 secures to the suture 762 without significant deformation of the suture 762.

### **Embodiment of Figure 31**

**[0400]** Referring to FIG. 31, the suture retainer 780 includes a first section 782 and a second section 784 formed separately from each other. However, it is contemplated that the two sections 782 and 784 could be interconnected by a flexible connector section. The flexible connector section may be formed as one piece with the suture retainer first section 782 and the second section 784.

**[0401]** The first section 782 of the suture retainer 780 includes a top surface 786 and a bottom surface 788. The bottom surface 788 includes a pair of parallel extensions 790 and 792 extending substantially along the length of the bottom surface 788.

**[0402]** The second section 784 of the suture retainer 780 includes a top surface 794 and a bottom surface 796, wherein the top surface 794 includes a pair of parallel channels 798 and 800. The parallel channels 798 and 800 are configured for receiving the parallel extensions 790 and 792 of the first section 782.

**[0403]** The end portions of the parallel extensions 790 and 792 each have a pointed configuration. Thus, the end portions of the parallel extensions 790 and 792 each include a flat side surface area which intersects a flat side surface area at a linear point or peak. Therefore, there is line contact between the end portions and the flat bottom surface of the parallel channels 798 and 800.

**[0404]** By forming the end portions of the parallel extensions 790 and 792 with a pointed configuration, the end portions are effective to function as energy directors for ultrasonic vibratory energy. The pointed end portions of the parallel extensions 790 and 792 are effective to direct ultrasonic vibratory energy transmitted from the first section 782 of the suture retainer 780 to the ends of the parallel extensions 790 and 792 and to the bottom surfaces of the parallel

channels 798 and 800. The pointed configuration of the end portions of the parallel extensions 790 and 792 concentrates the energy and facilitates melting of the material of the parallel extensions 790 and 792. To a lesser extent, the material of the second section 784 of the retainer 780 is melted adjacent to the parallel channels 798 and 800. This results in a secure bonding and interconnection between the first and second sections 782 and 784 of the retainer 780.

**[0405]** When a suture 802 and suture retainer 780 are to be used to secure the human body tissue, the suture 802 is positioned relative to the body tissue. The suture 802 includes ends 804 and 806 which are formed separately from the suture retainer first and second sections 782 and 784. The suture 802 is positioned relative to human body tissue with the ends 804 and 806 extending away from an outer side surface of the body tissue. The suture 802 may be connected with the body tissue in the same manner as illustrated schematically in FIG. 1 if desired. A predetermined tension force is then applied to the suture ends 804 and 806.

**[0406]** The suture retainer sections 782 and 784 are positioned in engagement with the suture ends 804 and 806, wherein the suture ends 804 and 806 are interposed between the parallel extensions 790 and 792 of the suture retainer first section 782. The suture retainer first section 782 engages the suture retainer second section 784, such that the parallel extensions 790 and 792 are positioned within the parallel channels 798 and 800 and the suture ends 802 and 804 are interposed between the bottom surface 788 of the first section 782 and the top surface 794 of the second section 784 of the suture retainer 780. The suture retainer 780 is pressed against the body, resulting in the body tissue being pressed between the suture retainer 780 and the portion of the suture 802 connected with the body tissue. A force distribution member could be provided between the suture retainer 780 and body tissue if desired.

**[0407]** The suture retainer sections 782 and 784 are bonded together securing the suture ends 804 and 806 using ultrasonic vibratory energy transmitted to the suture retainer 780 as previously described in relation to FIGS. 30A- 30B. However, in the present embodiment the heat in the suture retainer 780 will tend to be concentrated adjacent to the parallel extensions 790 and 792 and the parallel channels 798 and 800.

## **Embodiment of Figure 32**

**[0408]** Referring to FIG. 32, the suture retainer 810 includes a first section 812 and a second section 814 formed separately from each other. However, it is contemplated that the two sections 812 and 814 could be interconnected by a flexible connector section. The flexible connector section may be formed as one piece with the first section 812 and the second section 814 of the suture retainer 810.

**[0409]** The first section 812 of the suture retainer 810 includes a top surface 816 and a bottom surface 818. The bottom surface 818 includes a center post 820 extending therefrom. The second section 814 of the suture retainer 810 includes a top surface 822 and a bottom surface 824, wherein the top surface 822 includes a center flange 826 defining a passage 828 configured for receiving the center post 820.

**[0410]** The end portion of the center post 820 has a pointed configuration. Thus, the end portion of the center post 820 includes a substantially conical shape forming a point. Therefore, there is a point of contact between the end portion of the center post 820 and the flat bottom surface of the passage 828 of the second section 814.

**[0411]** By forming the end portion of the center post 820 with a pointed configuration, the end portion of the center post 820 is effective to function as energy director for ultrasonic vibratory energy. The pointed end portion of the center post 820 is effective to direct ultrasonic vibratory energy transmitted from the first section 812 to the ends of the center post 820 to the bottom surfaces of the passage 828 of the second section 814. The pointed configuration of the end portion of the center post 820 concentrates the energy and facilitates melting of the material of the center post 820. To a lesser extent, the material of the second section of the retainer 810 is melted adjacent to the bottom surfaces of the passage 828. This results in a secure bonding and interconnection between the first and second sections 812 and 814 of the retainer 810.

**[0412]** When a suture 830 and suture retainer 810 are to be used to secure the human body tissue, the suture 830 is positioned relative to the body tissue. The suture 830 includes ends

832 and 834 which are formed separately from the suture retainer first and second sections 812 and 814. The suture 830 is positioned relative to human body tissue with the ends 832 and 834 extending away from an outer side surface of the body tissue. The suture 830 may be connected with the body tissue in the same manner as illustrated schematically in FIG. 1 if desired. A predetermined tension force is then applied to the suture ends 832 and 834.

[0413] In use, the suture ends 832 and 834 are wrapped around the center post 820 of the suture retainer first section 812. The center post 820 and wrapped suture ends 832 and 834 are inserted into the passage 828 on the top surface 822 of the suture retainer second section 814. The suture retainer 810 is pressed against the body, resulting in the body tissue being pressed between the suture retainer 810 and the portion of the suture 830 connected with the body tissue. A force distribution member could be provided between the suture retainer 830 and body tissue if desired.

[0414] The suture retainer sections 812 and 814 are bonded together securing the suture ends 832 and 834 using ultrasonic vibratory energy transmitted to the suture retainer 810 as previously described in relation to FIGS. 30A- 30B. However, in the present embodiment the heat in the suture retainer 810 will tend to be concentrated adjacent to the center post 820 and passage 828.

### **Embodiment of Figures 33A-33B**

[0415] Referring to FIGS. 33A-33B, the suture retainer 840 includes a first section 842 and a second section 844 formed separately from each other. The first section 842 of the suture retainer 840 includes a first end 846, a second end 848, and a first and second surface 850 and 852 interposed between the first and second ends 846 and 848. The second section 844 of the suture retainer 840 includes a first end 854, a second end 856, and a first and second surface 858 and 860 interposed between the first and second ends 854 and 856. The first section first end 846 and the second section first end 854 are coupled such that the first section second surface 850 and the second section first surface 858 are facing each other. The first section second end 848

can include an engagement member 861 configured for engaging the second section top surface 858.

[0416] The end portion of the engagement member 861 has a pointed configuration. Thus, the engagement member 861 includes a flat side surface area which intersects a flat side surface area at a linear point or peak. Therefore, there is line contact between the end portion of the engagement member 861 and the second section top surface 858.

[0417] By forming the end portion of the engagement member 861 with a pointed configuration, the end portion of the engagement member 861 is effective to function as energy director for ultrasonic vibratory energy. The pointed end portion of the engagement member 861 is effective to direct ultrasonic vibratory energy transmitted from the first section 842 to the second section top surface 858. The pointed configuration of the end portion of the engagement member 861 concentrates the energy and facilitates melting of the material of the engagement member 861. To a lesser extent, the material of the second section of the retainer 840 is melted adjacent to the engagement member 861. This results in a secure bonding and interconnection between the first and second sections 842 and 844 of the retainer 840.

[0418] When a suture 862 and suture retainer 840 are to be used to secure the human body tissue, the suture 862 is positioned relative to the body tissue. The suture 862 includes ends 864 and 866 which are formed separately from the suture retainer first and second sections 842 and 844. The suture 862 is positioned relative to human body tissue with the ends 864 and 866 being substantially parallel to an outer side surface of the body tissue, such that the suture 862 forms a loop. The suture 862 may be connected with the body tissue in the same manner as illustrated schematically in FIG. 1 if desired. A predetermined tension force is then applied to the suture ends 864 and 866.

[0419] The suture retainer sections 842 and 844 are positioned in engagement with the suture ends 864 and 866, wherein the suture ends 864 and 866 are interposed between the first section second surface 850 and the second section first surface 858, wherein the engagement member 861 hold the suture 862 within the suture retainer 840.

**[0420]** The suture retainer sections 842 and 844 are bonded together securing the suture ends 864 and 866 using ultrasonic vibratory energy transmitted to the suture retainer 840 as previously described in relation to FIGS. 30A- 30B. The anvil and horn engage the first section first surface 846 and the second section second surface 852. The anvil and horn are pressed against the first section first surface 846 and the second section second surface 852 with a predetermined force to firmly press the first section second surface 848 and the second section first surface 850 against the ends 864 and 866 of the suture 862.

**[0421]** In an alternative embodiment, as shown in FIGS. 37A-37B, the suture retainer first section 842 and second section 844 are hingedly connected. The hinged section 868 collapses when the first section second surface 850 and the second section first surface 858 are compressed together, such that the first section second surface 850 and the second section first surface 858 remain substantially parallel. Additionally, the first section second surface 850 and the second section first surface 858 can include opposing serrated surfaces 870. The opposing serrated surfaces 870 are configured to grip the suture ends 864 and 866 when compressed. The opposing serrated surfaces also increase the surface area of the first section second surface 850 and the second section first surface 858, providing an increase bonding area for welding.

#### **Embodiment of Figures 34A-34B**

**[0422]** Referring to FIGS. 34A-34B, the suture retainer 880 has a generally rectangular configuration and includes a top surface 882 and a bottom surface 884, with the top surface 882 including a pair of parallel grooves 886 and 888 extending along the length of the suture retainer 880. The parallel grooves 886 and 888 each have a radius which is greater than the radius of the suture 890. The major side surfaces 892 and 894 of the grooves 886 and 888 are greater than the diameter of the suture, such that each of the suture ends 896 and 898 are disposed one each in grooves 886 and 888.

**[0423]** The end portions of the major side surfaces 892 and 894 of the grooves 886 and 888 each have a pointed configuration. Thus, the end portions major side surfaces 892 and 894 of the grooves 886 and 888 each include a flat side surface area which intersects a flat side

surface area at a linear point or peak. Therefore, there is line contact between the end portions and horn 902.

[0424] The suture retainer 880 is positioned in an engagement with the suture, wherein the suture ends 896 and 898 are disposed within the grooves 886 and 888. The suture retainer 880 is pressed against the body tissue with a predetermined force. This results in the body tissue being pressed between the suture retainer 880 and the portion of the suture 890 connected with the body tissue. A force distribution member could be provided between the suture retainer 880 and body tissue if desired.

[0425] When the suture and suture retainer 880 are to be used to secure the human body tissue, the suture is positioned relative to the body tissue. The suture may be positioned relative to the body tissue in the manner illustrated schematically in FIG. 1. A predetermined tension force is then applied to the suture ends sections 896 and 898 of the suture.

[0426] To effect the transmission of ultrasonic vibratory energy to the suture retainer 880, an anvil 900 is moved into engagement with the suture retainer bottom surface 884. A horn or acoustic tool 902 is moved into engagement with the suture retainer top surface 882. The anvil 900 and horn 902 are pressed against the suture retainer top surface 882 and bottom surface 884 with a predetermined force.

[0427] While the anvil 900 and horn 902 are being pressed against the suture retainer 880 with a predetermined force, ultrasonic vibrations are transmitted from the horn 902 to the suture retainer 880. The ultrasonic vibrations transmitted to the suture retainer 880 create frictional heat and cause portions of the material of the suture retainer 880 to be heated into the transition temperature range for the material. As the material of the suture retainer 880 is heated into its transition temperature range, the material loses some of its rigidity and softens. The material of the suture retainer 880 does not melt and become liquid. The heat in the suture retainer 880 will tend to be concentrated adjacent to the grooves 886 and 888 in the major side surfaces 892 and 894.

**[0428]** As the material of the suture retainer 880 is heated and softened by the ultrasonic vibratory energy, the major side surfaces 892 and 894 are compressed by a force applied against the anvil 900 and horn 902. For example, the force applied to the suture retainer 880 can be substantially between 1 to 20 lbs. As this occurs, the material of the major side surfaces 892 and 894 is plastically deformed and pressed over the suture ends 896 and 898 and the grooves 886 and 888 in the suture retainer 880.

**[0429]** When this has occurred, the transmission of ultrasonic energy to the suture retainer 880 is interrupted. However, the force applied against the suture retainer 880 top surface 882 and bottom surface 884 is maintained. It is believed that it may be desired to increase the force applied against the top surface 882 and bottom surface 884 by the anvil 900 and horn 902 as the application of ultrasonic vibratory energy to the suture retainer 880 is interrupted. While the clamping force applied by the anvil 900 and horn 902 is maintained or increased, the deformed suture retainer 880 secures the suture ends 896 and 898 without significant deformation of the suture.

**[0430]** To facilitate the flow of the plastically deformed sections of the suture retainer 880 over the suture ends 896 and 898 and the suture retainer grooves 886 and 888, the horn 902 can include shaped sections. The horn 902 includes a first and second curved section 904 and 906 for engaging the major side surfaces 892 and 894 of the suture retainer 880. The first and second curved sections 904 and 906 are shaped to force the plastically deformed major side surfaces 892 and 894 over the suture ends 886 and 888 and the grooves 886 and 888 when the force is applied.

### **Embodiment of Figure 35**

**[0431]** Referring to FIG. 35, the suture retainer 910 has a generally rectangular configuration and includes a top surface 912 and a bottom surface 914, wherein the top surface includes a pair of parallel grooves 916 and 918 separated by a center extension 920 such that one each of the suture ends 922 and 924 are disposed in a groove 916 and 918.

**[0432]** The suture retainer 910 is positioned in an engagement with the suture, wherein the suture ends 922 and 924 are disposed with the grooves 916 and 918. The suture retainer 910 is pressed against the body tissue with a predetermined force. This results in the body tissue being pressed between the suture retainer 910 and the portion of the suture connected with the body tissue. A force distribution member could be provided between the suture retainer 910 and body tissue if desired.

**[0433]** The suture retainer 910 secures to the suture ends 922 and 924 using ultrasonic vibratory energy transmitted to the suture retainer 910 as previously described in relation to FIGS. 34A-34B. However, in the present embodiment the heat in the suture retainer 910 will tend to be concentrated adjacent to the center extension 920. As this occurs, the material of the center extension 920 of the suture retainer 910 is plastically deformed and pressed over the suture ends 922 and 924 and the suture retainer grooves 916 and 918.

**[0434]** To facilitate the flow of the plastically deformed sections of the suture retainer 910 over the suture ends 922 and 924 and the suture retainer grooves 916 and 916, the horn 926 can include shaped sections. The horn 926 includes a first and second curved section 928 and 930 separated by a point tip 932 for engaging the suture retainer center extension 920. The pointed tip 932 of the horn 926 directs the ultrasonic energy into the center extension 920. As the center extension 920 is heated, the first and second curved sections 928 and 930 are shaped to force the plastically deformed center extension 920 over the suture ends 922 and 924 and the suture retainer grooves 916 and 916 when the force is applied.

**[0435]** It is contemplated that the horn can include any shaped section which focus the energy and directs the plastically deformed section of the suture retainer over the suture ends, securing the suture retainer and the suture end. Referring to FIGS. 36A-36C, exemplary horn shapes are provided which include, but are not limited to, a convex surface, a concave surface, a triangular surface, inverted triangular surface, etc.

**[0436]** The suture retainer of the present invention can include a textured surface. The textured surface increases the surface area, thereby providing an increased bonding area. For

example, as shown in FIGS. 37A and 37B, the first section second surface 850 and the second section first surface 858 of the suture retainer 840 includes a texture surface, namely a serrated surface. The textured surface increases surface areas of the first section second surface 850 and the second section first surface 858, providing an increased bonding area. The textured surface can include any geometric pattern which provides an increase in surface bonding area. Additionally, texture surface provides an increase in the surface friction between the suture retainer and the suture.

### **Embodiment of Figure 38**

[0437] Referring to FIG. 38, the suture retainer 940 is a heat shrink material, wherein the suture retainer 940 is wrapped around the suture 942. While the suture 942 is being pulled straight under the influence of tension in the suture due to the force and while the suture retainer 940 is being pressed against the upper layer of body tissue or against a suitable force distribution member, the suture retainer 940 is heated, causing the suture retainer to shrink around and grip the suture 940. In accordance with one of the features of the invention, the suture retainer 940 is heated by the application of ultrasonic vibratory energy to the suture retainer. The ultrasonic vibratory energy is converted into heat by the molecules of the suture retainer 940. Thus, the mechanical ultrasonic vibrations applied against the suture retainer 940 cause molecular vibration of the material of the suture retainer and a heating of the suture retainer.

[0438] The suture retainer 940 can be substantially cylindrical in shape, wherein the suture ends 944 and 946 are inserted through the suture retainer 940. Additionally, the suture retainer can be of other geometric shapes configured for receiving the suture.

### **Embodiment of Figure 39**

[0439] In the previous embodiments, a suture retainer and suture has been utilized to interconnect sections of a suture to secure tissue segments. In the embodiment of the invention illustrated in FIGS. 39, the tissue securing system includes a retainer device 960 to secure body tissue, either soft body tissue to soft body tissue or soft body tissue to hard body tissue.

[0440] The retainer device 960 includes first and second sections 962 and 964 interconnected by a mid-section 966. The first section 962 includes an engagement member 968 and the second section 964 includes slotted member 970 configured for receiving the engagement member 968.

[0441] The end portion of the engagement member 968 has a pointed configuration. Thus, the engagement member 968 includes a flat side surface area which intersects a flat side surface area at a linear point or peak. Therefore, there is line contact between the end portion of the engagement member 968 and the second section slotted member 970.

[0442] By forming the end portion of the engagement member 968 with a pointed configuration, the end portion of the engagement member 968 is effective to function as energy director for ultrasonic vibratory energy. The pointed end portion of the engagement member 968 is effective to direct ultrasonic vibratory energy transmitted from the first section 962 to the second section slotted member 970. The pointed configuration of the end portion of the engagement member 968 concentrates the energy and facilitates melting of the material of the engagement member 968. To a lesser extent, the material of the second section 964 of the retainer 960 is melted adjacent to the slotted member 970. This results in a secure bonding and interconnection between the first and second sections 982 and 964 of the retainer 960.

[0443] The retainer device 960 secures upper and lower layers of soft, human body tissue in linear apposition with each other. Thus, the two layers of human body tissue are approximated and held against movement relative to each other by retainer device 960. Pressing the two layers together with the retainer device 940 promotes healing of the tissue.

[0444] Although the retainer device 960 has been described as being used to hold layers of soft tissue in linear apposition with each other, it is contemplated that the tissue securing system may be used in many different locations in a patient's body to secure tissue. For example, the retainer device 960 could be utilized to secure soft tissue such as a ligament or tendon against movement relative to a bone. Alternatively, the retainer device 960 could be utilized to interconnect portions of a flexible conduit, such as a blood vessel or intestine. It

should be understood that the retainer device 960 may be used with either hard body tissue or soft body tissue or both hard and soft body tissue.

[0445] In use, the retainer device 960 is used to secure the layers of soft tissue, by passing the first and second sections 962 and 964 through the tissue layers. The mid-section 966 of the retainer device 960 should proximate to the upper surface of the upper tissue layer.

[0446] In accordance with a feature of this embodiment of the invention, the first and second sections 962 and 964 of the retainer device are interconnected, such that the engagement member 968 is positioned within the slotted member 970. The first and second sections 962 and 964 are heated and bonded together. Heating first and second sections 962 and 964 softens the material of engagement member 968 and the slotted member 970, allowing them to be plastically deformed and bonded together. The first and second sections 962 and 964 can be bonded together using ultrasonic vibratory energy as has previously been described.

#### **Embodiment of Figures 40-47**

[0447] Referring to FIGS. 40-47 the suture retainer 1030 is utilized to fixedly interconnect opposite portions 1032 and 1034 of a suture 1036. The portions 1032 and 1034 of the suture 1036 extend in opposite directions through the retainer 1030. An intermediate portion 1038 of the suture extends between the portions 1032 and 1034 and extends around body tissue 1040 to the retainer 1030. It should be understood that the suture 1036 and retainer 1030 could be connected with each other and/or the body tissue 1040 in a manner which is different than the specific manner illustrated in Fig. 40. For example, the portions 1032 and 1034 of the suture 1036 may extend in the same direction from the retainer 1030.

[0448] It is contemplated that the suture 1036 and retainer 1030 may be utilized to secure body tissue 1040 in many different ways. For example, the suture 1036 and retainer 1030 may be utilized to secure one piece of body tissue to another piece of body tissue. The suture 1036 and retainer 1030 may be utilized to secure soft body tissue to hard body tissue (bone). The suture 1036 and retainer 1030 may be utilized to connect hard body tissue to hard body tissue in

the manner disclosed in U.S. Patent No. 6,238,395. The suture 1036 and retainer 1030 may be disposed entirely within a patient's body or may engage a surface area on the patient's body.

**[0449]** It is contemplated that the suture 1036 can be constructed of a single filament or of a plurality of filaments. The suture 1036 may be formed of biodegradable or nonbiodegradable material. Similarly, the retainer 1030 may be formed of biodegradable or nonbiodegradable material.

**[0450]** The retainer 1030 includes a lower or base section 1046 (Figs. 41 and 42) and an upper or cover section 1048. The portions 1032 and 1034 of the suture 1036 extend through passages 1052 and 1054 (Figs. 41 and 46) formed between the upper and lower sections 1046 and 1048 of the retainer 1030. The passages 1052 and 1054 have a cross sectional area which is slightly greater than the cross sectional area of the suture 1036 (Fig. 46). Therefore, the portions 1032 and 1034 of the suture 1036 can be readily pulled through the passages 1052 and 1054 when the retainer 1030 is in the initial or undeformed condition illustrated in Fig. 46. It should be understood that the passages 1052 and 1054 could have a configuration other than the configuration illustrated in Fig. 46.

**[0451]** Once the suture 1036 has been tensioned with a desired force, the retainer 1030 is plastically deformed in the manner illustrated schematically in Fig. 47. This results in the portions 1032 and 1034 of the suture 1036 being securely gripped between the lower and upper sections 1046 and 1048 of the retainer 1030. The portions 1032 and 1034 of the suture 1036 are gripped with a clamping action which holds them against movement relative to each other and to the retainer 1030. This results in the desired tension being maintained in the suture 1036.

**[0452]** The lower section 1046 of the retainer 1030 includes a right (as viewed in Fig. 42) recess 1058 and a left recess 1060. The right and left recesses 1058 and 1060 have the same configuration and are disposed the same distance from a central axis of the circular lower section 1046 of the retainer 1030. Although the recesses 1058 and 1060 could have many different configurations, the illustrated recesses have elongated configurations with parallel longitudinal central axes which extend perpendicular to the central axis of the circular lower section 1046.

**[0453]** The upper section 1048 has a circular body 1064 from which right (as viewed in Fig. 42) and left projections 1066 and 1068 extend. The right and left projections 1066 and 1068 have the same cross sectional configuration which corresponds to the cross sectional configuration of the recesses 1058 and 1060 (Figs. 43-46). The projections 1066 and 1068 have an elongated configuration with parallel longitudinal central axes which extend perpendicular the central axis of the circular body 1064 of the upper section 1048 of the retainer 1030. The projections 1066 and 1068 are disposed the same distance from a central axis of the upper section 1048. It is contemplated that the projections 1066 and 1068 could have a configuration which is different than the specific configuration illustrated in Figs. 43 – 46.

**[0454]** A center projection 1072 is disposed on the lower section 1046 of the retainer 1030 at a location midway between the right and left recesses 1058 and 1060 (Figs. 42, 43 and 46). The left and right projections 1066 and 1068 on the upper section 1048 of the retainer 1030 are telescopically received in the right and left recesses 1058 and 1060 in the lower section 1046 of the retainer 1030 (Figs. 41, 42, and 46). This results in the upper section 1038 of the retainer being positioned in a coaxial relationship with the lower section 1036 of the retainer. The center projection 1072 is disposed midway between the right and left projections 1066 and 1068 when they engage the right and left recesses 1058 and 1060. The right and left recesses 1058 and 1060 cooperate with the right and left projections 1066 and 1068 to orient the upper section of the retainer 1048 with the longitudinal axes of the right and left projections 1066 and 1068 extending parallel to the longitudinal axis of the center section 1072.

**[0455]** When the right and left projections 1066 and 1068 are disposed in the right and left recesses 1058 and 1060 (Fig. 46), the center projection 1072 cooperates with the right and left projections to partially form the passages 1052 and 1054. The bottom (as viewed in Fig. 46) of the passage 1052 is formed by a gripper surface area 1078. The bottom of the passage 1054 is formed by a gripper surface area 1080.

**[0456]** The gripper surface areas 1078 and 1080 on the lower section 1046 face and are parallel to gripper surface areas 1082 and 1084 (Fig. 46) on the upper section 1048. The gripper surface areas 1078, 1080, 1082 and 1084 cooperate with the projections 1066, 1068 and 1072 to

define the parallel passages 1052 and 1054. The gripper surface areas 1078, 1080, 1082 and 1084 may be roughened or knurled to enhance their ability to grip the suture 1036.

**[0457]** The right and left projections 1066 and 1068 have flat parallel longitudinally extending inner side surfaces 1088 and 1090 (Figs. 43 and 46). The inner side surfaces 1088 and 1090 on the projections 1066 and 1068 extend perpendicular to the gripper surface areas 1082 and 1084 on the circular body 1064 of the upper section 1048 of the retainer 1030. In addition, the right and left projections 1068 and 1070 have outer side surfaces 1092 and 1094 which extend parallel to the inner side surfaces 1088 and 1090.

**[0458]** The center projection 1072 has parallel right and left side surfaces 1096 and 1098 which extend perpendicular to the gripper surface areas 1078 and 1080 on the lower section 1046 (Fig. 43). When the right and left projections 1066 and 1068 on the circular body 1064 of the upper section 1048 of the retainer 1030 are disposed in the right and left recesses 1058 and 1060 on the lower section 1046 (Fig. 46), the right and left side surfaces 1096 and 1098 on the center projection 1072 extend parallel to the inner side surfaces 1088 and 1090 on the right and left projections 1066 and 1068.

**[0459]** The passages 1052 and 1054 through the retainer 1030 are formed by flat surfaces on the lower and upper sections 1046 and 1048 of the retainer. The flat side surfaces which form the parallel passages 1052 and 1054 are effective to guide a leading end of a portion of a suture 1036 as the suture is inserted into the passage. Thus, the leading end of the portion 1032 of the suture is directed by the side surfaces 1078, 1088, 1082, and 1098 (Fig. 46) formed on the lower section 1046, right projection 1066, body 1064 and center projection 1072 respectively. Similarly, the leading end of the portion 1034 of the suture 1036 is directed by the side surfaces 1080, 1090, 1084 and 1096 formed on the lower section 1046, left projection 1068, body 1064 and center projection 1072. By forming the passages 1052 and 1054 with elongated side surfaces, insertion of the portions 1032 and 1034 of the suture 1036 into the passages is facilitated. This is because once a portion 1032 or 1034 of the suture 1036 has been inserted into one of the passages 1052 or 1054, the side surfaces of the passage maintain the leading end of

the suture in a desired relationship with the passage as the suture continues to be moved into the passage.

**[0460]** The center projection 1072 is effective to position the portions 1032 and 1034 of the suture 1036 so that they are disposed on opposite sides of and equal distances from a central axis of the retainer 1030. This results in off setting movements being applied to the retainer 1030 by forces transmitted to the retainer from the portions 1032 and 1034 of the suture 1036. Therefore, there is little or no tendency for the retainer 1030 to rotate or flip relative to the body tissue 1040.

**[0461]** The right and left projections 1066 and 1068 on the upper section 1048 of the retainer 1030 are disposed in the recesses 1058 and 1060 in the lower section 1046 of the retainer 1078 (Fig. 46) during insertion of the portions 1032 and 1034 of the suture 1036 into the passages 1052 and 1054 in the retainer 1030. To hold the projections 1066 and 1068 in the recesses 1058 and 1060, there is an interference fit between the projections and the recesses. Thus, the distance between an outer side surface 1102 of the right recess 1058 (Fig. 56) and an inner side surface 1104 of the right recess is slightly less than the distance between the outer side surface 1092 and inner side surface 1088 on the right projection 1066. The resulting interference between the right projection 1066 and the right recess 1058 is effective to hold the right projection in the right recess.

**[0462]** Similarly, the left recess 1060 has parallel outer and inner side surfaces 1110 and 1112. The outer and inner side surfaces 1110 and 1112 of the left recess 1060 are spaced apart by distance which is slightly less than the distance between the outer side surface 1094 and inner side surface 1090 on the left projection 1068. When the left projection 1068 is pressed into the left recess 1060, the resulting interference between the side surfaces 1090 and 1094 on the projection 1068 and the side surfaces 1110 and 1112 on the recess 1060 hold the left projection in the left recess. The side surfaces 1102, 1104, 1110 and 1112 on the recesses 1058 and 1060 extend parallel to the side surfaces 1096 and 1098 on the center projection 1072 and perpendicular to the gripper surface areas 1078 and 1080 on the lower section 1046.

**[0463]** The interference fit between the projections 1066 and 1068 on the upper section 1048 of the retainer with the recesses 1058 and 1060 in the lower section 1046 of the retainer holds the two sections of the retainer against movement relative to each other during insertion of the portions 1032 and 1034 of the suture 1036 into the passages 1052 and 1054. However, it is contemplated that the upper section 1048 and lower section 1046 of the retainer 1030 may be held against movement relative to each other by means other than an interference fit. For example, latch surfaces on the projections 1066 and 1068 may engage latch surfaces formed on the sides of the recesses 1058 and 1060. These latch surfaces may have a generally wedge shaped configuration. Alternatively, a pin may extend through at least a portion of the lower section 1046 of the retainer and the projections 1066 and 1068 on the upper section 1048 of the retainer to hold the upper section against movement relative to the lower section.

**[0464]** The lower section 1046 and upper section 1048 of the retainer 1030 are formed as two separate pieces. However, it is contemplated that the lower and upper sections 1046 and 1048 of the retainer 1030 could be formed as one piece. If this is done, relatively weak connectors may be provided between the projections 1066 and 1068 and the base section 1046 to hold the base and upper sections 1046 and 1048 in a desired spatial relationship with each other during insertion of the portions 1032 and 1034 of the suture 1036 into the passages 1052 and 1054. The weak connectors may be broken to enable the portions 1032 and 1034 of the suture 1036 to be gripped between the retainer sections 1046 and 1048. Alternatively, a flexible strap may be formed between the base section 1046 and upper section 1048. By deflecting the strap, the projections 1066 and 1068 may be inserted into the recesses 1058 and 1060.

**[0465]** When the right and left projections 1066 and 1068 are telescopically inserted into the right recess 1058 and left recess 1060, the leading or lower (as viewed in Fig. 46) end portions of the projections engage flat bottom surfaces 1118 and 1120 of the recesses 1058 and 1060 (Fig. 56). The flat bottom surfaces 1118 and 1120 extend parallel to the gripper surface areas 1078 and 1080 on the lower section 1046 and perpendicular to the side surfaces 1102, 1104, 1110 and 1112 of the recesses 1058 and 1060. Engagement of end portions 1124 and 1126 of the projections 1066 and 1068 with the bottom surfaces 1118 and 1120 of the recesses 1058

and 1060 positions the lower and upper sections 1046 and 1048 of the retainer relative to each other and determines the size of the passages 1052 and 1054. This results in the passages 1052 and 1054 being sized so as to have a cross sectional area which is slightly greater than the cross sectional area of the portions 1032 and 1034 of the suture 1036 to enable the suture to be readily inserted into the passages.

**[0466]** The center projection 1072 has a flat upper side surface 1130 which extends parallel to the gripper surfaces 1078, 1080, 1082 and 1084. The upper side surface 1130 on the center projection 1072 is spaced from the upper section 1048 when the end portions 1124 and 1126 of the projections 1066 and 1068 are in engagement with the bottom surfaces 1118 and 1120 of the recesses 1058 and 1060. However, if desired, the center projection 1072 may be disposed in engagement with the upper section 1048 when the end portions 1124 and 1126 of the projections 1066 and 1068 are in engagement with the bottom surfaces 1118 and 1120 of the recesses 1058 and 1060.

**[0467]** When the end portions 1124 and 1126 of the projections 1066 and 1068 are in engagement with the bottom surfaces 1118 and 1120 of the recesses 1058 and 1060, the portions 1032 and 1034 of the suture 106 can be freely moved in the passages 1052 and 1054 to enable the retainer 1060 to be slid along the suture 1036 to a desired position relative to the body tissue 1040. The retainer 1030 may be slid along the suture 1036 under the influence of force manually applied against the retainer or under the influence of force applied against the retainer by a surgical instrument, such as forceps. As this occurs, the intermediate portion 1038 (Fig. 40) of the suture is tightened around the body tissue with a desired force.

**[0468]** Once the retainer 1030 has been positioned in a desired location relative to the body tissue 1040 and the suture 1036 tensioned with a predetermined force, the retainer is plastically deformed from the initial condition illustrated in Fig. 46 to the condition illustrated in Fig. 47. Plastic deformation of the retainer 1030 results in the size of the passages 1052 and 1054 being decreased. In addition, the upper side 1130 on the center projection 1072 moves into engagement with the upper section 1048 of the retainer 1030. Engagement of the center projection 1072 with the upper section 1048 of the retainer 1030 tends to limit the extent to which

the lower and upper section 1046 and 1048 of the retainer are pressed together to thereby limit plastic deformation of the retainer 1030.

[0469] If the retainer 1030 is constructed so that the center projection 1072 engages the upper section 1048 of the retainer when the end portions 1124 and 1126 of the projections 1066 and 1068 are in engagement with the bottom surface areas 1118 and 1120 of the recesses 1058 and 1060, the center projection would also be deformed when the retainer is plastically deformed from the initial condition of Fig. 46 to the condition of Fig. 47. With this construction of the retainer 1030, the center projection 1072 would be deformed to the same extent as the projections 1066 and 1068. Therefore, the center projection 1072 may be formed with an upper end portion which has the same configuration as the lower end portions 1124 and 1126 of the projections 1066 and 10168.

[0470] To plastically deform and interconnect the lower and upper sections 1046 and 1048 of the retainer 1030, a member 1140 (Fig. 47) is moved into a groove 1142 in the lower section 1046. The member 1140 acts as an anvil to hold the lower section 1048 during welding. The member 1040 is shown as a bar, it is also contemplated that the member 1040 can be a flat plate for engaging the flat outside surface of the lower section 1046, wherein the plate can include a lip around its peripheral edge to prevent the lower section 1046 from moving during welding.

[0471] In addition, a second member 1144 engages a flat outer side surface 1146 on the upper section 1048 of the retainer 1030. The lower and upper sections 1046 and 1048 of the retainer 1030 are firmly pressed together by force transmitted between the members 1140 and 1144 through the retainer. While the lower and upper sections 1046 and 1048 of the retainer 1030 are gripped between the members 1140 and 1144 with a clamping action, energy is transmitted from the member 1144 to the retainer 1030.

[0472] The energy applied to the retainer 1030 is effective to heat the end portions 1124 and 1126 of the projections 1066 and 1068 into a transition temperature range for the polymeric material of the projections. Force applied against the retainer 1030 by the members 1140 and

1144 (Fig. 47) causes the heat softened material of the projections 1066 and 1068 to flow in the recesses 1058 and 1060. To a lesser extent, material of the lower section 1046 is heated and also flows in the recesses 1058 and 1060.

[0473] As this occurs, the heated material of the projections 1066 and 1068 may be forced upward toward the portions 1032 and 1034 of the suture 1036. The heated material tends to bond to the portions 1032 and 1034 of the suture 1036. It should be understood that the extent of deformation and flow of the heat softened material of the projections 1066 and 1068 may be and probably will be greater than the extent illustrated schematically in Fig. 47.

[0474] If the retainer 1030 is constructed so that the center projection 1072 is deformed to the same extent as the projections 1066 and 1068, heat softened material of the center projection would flow into the passages 1052 and 1054. If the upper section 1048 of the retainer 1030 has the construction shown in Fig. 43, the upper end portion of the center projection would engage the flat lower side surface of the body 1064. However, the upper section 1048 of the retainer 1030 may be formed with a recess to receive the upper end portion of the center projection 1072. This recess may have the same configuration as the recesses 1058 and 1060 in the lower section 1046 of the retainer 1030.

[0475] If desired, the retainer 1030 may be constructed with the center projection 1072 extending from the upper section 1048 of the retainer. If this is done, the center projection 1072 from the upper section 1048 of the retainer may have the same configuration as the illustrated configuration of the center projection in Figs. 43 and 44. A recess may be provided in the lower section 1046 to receive a portion of a center projection from the upper section 1048 of the retainer 1030.

[0476] As the heated material of the projections 1066 and 1068 is caused to flow in the recess 1058 and 1060, the size of the passages 1052 and 1054 is decreased. This results in the portions 1032 and 1034 of the suture 1036 being firmly clamped between the gripper surface areas 1078 and 1080 on the lower section 1046 and the gripper surface areas 1082 and 1084 on the upper section 1048 of the retainer 1030. The force applied to the portions 1032 and 1034 of

the suture 1036 by the gripper surface areas 1078, 1080, 1082 and 1084 on the lower and upper sections 1046 and 1048 of the retainer 1030 is effective to deform the suture from the circular cross sectional configuration illustrated in Fig. 46 to a generally oval cross sectional configuration illustrated schematically in Fig. 47. Although the illustrated suture 1036 is a monofilament, it is contemplated that the suture could be formed by a plurality of filaments which are braided or twisted together.

[0477] The energy which is applied to the retainer 1030 by the member 1144 may be thermal energy, vibratory energy, or light energy. The energy may be transmitted by radio frequency waves, ultrasonic waves, heat waves, or light waves. The energy may be vibratory ultrasonic, light, heat, or radio frequency energy. Rather than positioning the member 1140 in the groove 1142 in the lower section 1046 of the retainer 1030, the groove 1142 may be omitted and a flat member, similar to the member 1144, may be pressed against the lower section 1046 of the retainer 1030. Energy may be transmitted to the retainer through either the member 1140 or the member 1144 or both of the members 1140 and 1144.

[0478] In the embodiment of the invention illustrated in Fig. 47, the portions 1032 and 1034 of the suture 1036 are clamped between the lower section 1046 and upper section 1048 of the retainer 1030. The clamping force applied against the portions 1032 and 1034 of the suture 1036 by the retainer 1030, holds the retainer and the portions of the suture against relative movement. This results in the suture 1036 and retainer 1030 being securely interconnected.

[0479] There is some bonding of material of the retainer to the portions 1032 and 1034 of the suture 1036 to further interconnect suture and the retainer. However, the amount of force and energy transmitted from the member 1140 or both of the members 1140 and 1144 to the retainer 1030 is sufficient to effect a plastic deformation of the material of the retainer without excessive plastic deformation of the material of the suture 1036. By avoiding excessive deformation of the material of the suture 1036, weakening of the suture is avoided. Thus, once the plastic deformation of the retainer 1030 has been effected by the transmission of force and energy to the retainer, the lower and upper sections 1046 and 1048 of the retainer are fixedly interconnected with the suture 1036 without significantly weakening of the suture.

**[0480]** The end portions 1124 and 1126 of the projections 1066 and 1068 have a pointed configuration. Thus, the end portion 1024 of the projection 1066 includes a flat side surface area 1150 which intersects a flat side surface area 1152 at a linear point or peak. Therefore, there is line contact between the end portion 1124 of the right projection 1066 and the flat bottom surface 1118 of the right recess 1058. Similarly, the end portion 1126 of the left projection 1168 has a flat side surface 1156 which intersects a flat side surface 1158 at a linear point or peak on the end portion 1126 of the left projection 1068. This results in line contact between the pointed end portion of the left projection 1068 and the flat bottom surface 1120 of the left recess 1060. However, the end portions 1124 and 1126 of the projections 1066 and 1068 may have a conical configuration if desired.

**[0481]** By forming the end portions 1124 and 1126 of the right and left projections 1066 and 1068 with a pointed configuration, the end portions of the projections are effective to function as energy directors for ultrasonic vibratory energy. The pointed end portions 1124 and 1026 of the right and left projections 1066 and 1068 are effective to direct ultrasonic vibratory energy transmitted from the member 1144 to the ends of the projections and to the bottom surfaces 1118 and 1120 of the recesses 1058 and 1060. The pointed configuration of the end portions 1124 and 1126 of the projections 1066 and 1068 concentrates the energy and facilitates melting of the material of the projections. To a lesser extent, the material of the lower section 1046 of the retainer 1030 is melted adjacent to the bottom surfaces 1118 and 1120. This results in a secure bonding and interconnection between the lower and upper sections 1046 and 1048 of the retainer 1030.

**[0482]** Referring to FIG. 29, the suture retainer illustrated in FIGS. 40-47 includes substantially flat edges 730, having a non-circular cross section when viewed from the top or the bottom surface. Additionally, the top or bottom surface can include a convex or concave surface.

**[0483]** Although generally shown as using ultrasonic energy, it is understood that in other embodiments the types of energy or combination of energies can be utilized to heat the suture retainer, suture, and retainer device. These types of energy or combination of energies can

include, but not be limited to, radio frequency (RF) energy, laser energy, infrared energy, microwave energy, ultrasound energy, and contact heating energy.

**[0484]** It is contemplated that the viable cells may be incorporated or positioned on the suture retainer of the present invention. The viable cells may be any desired type of viable cells. It is contemplated that the viable cells may correspond to cells which were in a damaged organ or other portion of a patient's body. More than one type of viable cell may be positioned on the suture retainer.

**[0485]** When the suture retainer is to be positioned in an organ, it is contemplated that the viable cells on the suture retainer will have characteristics associated with the characteristics of normal cells in the organ in which the support structure is to be positioned. Many organs contain cells which have different characteristics and perform different functions within the organ. It is contemplated that the viable cells on the suture retainer may have different characteristics corresponding to the different characteristics of cells of an organ. When the suture retainer is to be positioned outside of an organ, the cells positioned on the support structure may have any desired characteristic or combination of characteristics.

**[0486]** It is also contemplated that the viable cells can be pluripotent cells that are directed to differentiate into the desired cell type or types. One example of such cells is stem cells. The differentiation can be controlled by applying or exposing the cells to certain environmental conditions such as mechanical forces (static or dynamic), chemical stimuli (e.g. pH), and/or electromagnetic stimuli.

**[0487]** More than one type of cell may be positioned on the suture retainer. The type of cell positioned at a particular location on the suture retainer will be determined by the orientation of the support structure in a patient's body and by the specific type of tissue desired at a particular location in a patient's body. For example, stromal cells may be positioned at a location where foundation tissue is desired and another type of cell may be positioned at locations where it is desired to have tissue perform a special function.

**[0488]** In order to promote the attachment of the viable cells to the suture retainer, the suture retainer can be pretreated with an agent that promotes cell adhesion. One such agent is an organic substance based on a biofilm. A biofilm is a slimy, glue-like substance that forms when bacteria attach to surfaces exposed to water. Typically, colonies of biofilm bacteria are unwanted as they carry out a variety of detrimental reactions. However, a sterile biofilm may be used to promote initial attachment of cells to the suture retainer.

**[0489]** The sterile biofilm could be engineered to isolate the glue-like substance while eliminating the adverse properties of the bacteria. The resulting sterile glue-like substance would be used to help the cells stick to the suture retainer. The engineered biofilm could be added to the suture retainer in the laboratory that produces the suture retainer or just prior to the addition of the cells by the user. Alternatively, the biofilm and suture retainer could be combined intra-corporally.

**[0490]** This biofilm also could be used as an independent polysaccharide based adhesive with mild to moderate adhesion forces. The biofilm could serve as a surgical adhesion or grouting for cells, for tissue fixation (soft tissue to soft tissue, soft tissue to bone, etc.) and as a sealant.

**[0491]** Additionally, it is contemplated that pharmaceutical agents such as tissue inductive growth factors, additives, and/or other therapeutic agents may be provided on or incorporated into the suture retainer of the present invention. Such additives may include materials such as plasticizers, citrate esters, hexametholsebaccate, antibiotics (e.g., tetracyclines, penicillins, mefronidazole, clindamycin, etc.), to prevent infection, etc., or to accomplish other desired conditions or results, including for example, tissue inductive growth factors to promote a growth of tissue. Addition additives or therapeutic agents include osteoinductive, biocidal, or anti-infection substances. Suitable osteoinductive substances include, for example, growth factors. The growth factors may be selected from the group of IGF (insulin-like growth factors), TGF (transforming growth factors), FGB (fibroblast growth factors), EGF (epidermal growth factors), BMP (bone morphogenic proteins), and PDGF (platelet-derived growth factors).

**[0492]** The inductive growth factors, additives, and/or other therapeutic agents may be provided on or incorporated into the suture retainer prior to connection to the suture.

Alternatively, the inductive growth factors, additives, and/or other therapeutic agents may be provided on or incorporated after connection to the suture.

### **Embodiment of Figure 48-55**

**[0493]** Referring to FIGS. 48-51, the ultrasonic energy application apparatus 640 of FIG. 25 includes a rigid energy transmission member 1170 and a rigid tubular force transmitting member 1172 extends around and is coaxial with the cylindrical energy transmission member 1170. A biasing assembly 1174 continuously urges the force transmitting member 1172 toward the left (as viewed in Fig. 48) with a constant predetermined force. The illustrated embodiment of the biasing assembly 1174 includes a helical spring 1176 which is disposed between an annular flange 1178 on a reaction member 1180 and an annular piston 1182. The annular piston 1182 is fixedly connected to a housing 1184. The housing 1184 is connected to the tubular force transmitting member 1172. The reaction member 1180 is fixedly connected to a manually engagable handle 1186.

**[0494]** A trigger 1188 is pivotally connected with the handle 1186. The trigger 1188 is manually pivotal in a clockwise direction (as viewed in Figs. 48 and 50). Clockwise pivotal movement of the trigger 1188 transmits force through a yoke 1190. The force transmitted through the yoke 1190 moves the housing 1184 toward the right (as viewed in Figs. 48 and 50). This rightward movement of the housing 1184 moves a flange 1192 on the right (as viewed in Figs. 48 and 51) or distal end of the tubular force transmitting member 1172 away from a circular end surface 1194 on the energy transmission member 1170. The flange 1192 is shown as bar, it is also contemplated that the member 1040 can be a flat plate for engaging the flat outside surface of the suture retainer, wherein the plate can include a lip around its peripheral edge to prevent the movement of the suture retainer during welding.

**[0495]** The rightward (as viewed in Figs. 48 and 51) movement of the force transmitting member 1172 relative to the energy transmission member 1170 increases space between the

flange 1192 and end surface 1194 on the energy transmission member 1172. Increasing the space between the flange 1192 and the end surface 1194 enables the retainer to be positioned between the flange 1192 and the end surface 1194.

**[0496]** Once the retainer has been positioned in the space between the flange 1192 and the end surface 1194 on the energy transmission member 1170 (Figs. 48 and 51), the trigger 1188 is released. When the trigger 1188 is released, the biasing spring 1176 is effected to urge the housing 1184 toward the left (as viewed in Figs. 48 and 50). The leftward force applied by the spring 1176 against the housing 1184 is transmitted through the force transmitting member 1172 and flange 1192 to the retainer. This results in the retainer being clamped between the flange 1192 on the force transmitting member 1172 and end surface 1194 on the energy transmission member 1170. The spring 1176 is effective to apply a constant predetermined biasing force to the piston ring 1182. This constant biasing force is transmitted through the housing 1184 and force transmitting member 1172 to the retainer.

**[0497]** While the retainer is gripped with a predetermined constant force by the applicator assembly 640, the retainer is moved to a desired position relative to the body tissue. To position the retainer relative to the body tissue, the surgeon holds the handle 1186 of the applicator assembly 640 in one hand and tensions the suture with the other hand. The surgeon then manually applies force against the handle 1186 to slide the retainer along the tensioned suture toward the body tissue. The relatively long force transmitting member 1172 and energy transmitting member 1170 enable the applicator assembly 640 to move the retainer through a small incision to a remote location in a patient's body as the retainer slides along the suture.

**[0498]** During performance of a surgical procedure, the suture may be moved through a cannula to a location disposed within a patient's body. The suture is then positioned relative to the tissue at the remote location in the patient's body. However, it should be understood that the cannula may be omitted and the suture moved through an open incision.

**[0499]** Once the suture has been moved to the desired location relative to the tissue in the patient's body, the suture may be positioned in the retainer while the retainer is disposed outside

of the patient's body. Once the suture has been positioned in the retainer, the retainer is gripped by the applicator assembly 640. The flange 1192 on the force transmitting member 1172 and end surface 1194 on the energy transmission member 1170 of the applicator assembly 640 are effective to apply a predetermined constant force against opposite sides of the retainer to securely grip the retainer with the applicator assembly 640.

**[0500]** While the retainer is gripped by the applicator assembly 640, the suture is manually tensioned and the retainer is slid along the suture toward the body tissue. As the retainer is slid along the suture toward the body tissue, the applicator assembly 640 moves the retainer into the patient's body. As the retainer is moved into the patient's body, it is gripped with a constant predetermined force by the applicator assembly 640.

**[0501]** Alternatively, the retainer may be gripped by the applicator assembly 640 outside of the patient's body prior to positioning of the suture with the retainer. The suture may then be positioned in the retainer while the retainer is gripped by the applicator assembly 640. If desired, positioning of the suture in the retainer may be performed with the retainer inside the patient's body.

**[0502]** If the applicator assembly 640 is utilized to move the retainer through a cannula into the patient's body before the suture is positioned the retainer, suitable instruments may be utilized to grip the suture in the patient's body and to move the suture through the retainer. The instruments which engage the suture and move it through the retainer while the retainer is gripped by the applicator assembly 640, may extend through the cannula along with the applicator assembly. Alternatively, the instruments which move the suture through the retainer may be moved into the patient's body through a cannula spaced from the cannula through which the applicator assembly 640 moves the retainer into the patient's body. In order to minimize incisions in the patient's body, it may be preferred to utilize a single cannula to accommodate movement of the applicator assembly 640, retainer, suture positioning instruments, and the suture into the patient's body.

**[0503]** Once the retainer has been positioned in a desired relationship with body tissue and the suture, the suture is pulled with a predetermined force. This results in a predetermined tension being established in the suture. While the predetermined tension is maintained in the suture, the retainer is connected to suture, holding the suture against movement relative to the retainer. To effect plastic deformation of the retainer and connection of the retainer with the suture, energy is transmitted from an energy source 1196 (Fig. 48) through the energy transmission member 1170 to the retainer. At this time, the retainer is clamped between the flange 1192 on the force transmitting member 1172 and the end surface 1194 on the energy transmission member 1170.

**[0504]** In the illustrated embodiment of the applicator assembly 640, the energy source 1196 is a source of ultrasonic vibratory energy at a frequency above that which can normally be detected by the human ear, that is about 16 to 20 kilohertz. Although there are a wide range of frequencies which may be utilized, it is believed that it may be desirable to use ultrasonic energy having a frequency of between 20 kilohertz and 70 kilohertz. It is believed that it may be desired to use ultrasonic vibratory energy of a frequency between 39.5 and 41 kilohertz. When an actuated switch 1198 (Fig. 48) is closed, ultrasonic vibratory energy is transmitted through the energy transmission member 1170 to the retainer. The ultrasonic vibratory energy creates frictional heat which is effective to heat material of the retainer into its transition temperature range while the material of the suture remains at a temperature below its transition temperature range. The actuated switch 1198 can be external to the applicator assembly 640, for example, a foot peddle, or incorporated into the applicator assembly 640, for example a bottom of trigger.

**[0505]** However, it should be understood that even the entire transition temperature range for the suture could be co-extensive with the transition temperature range for the retainer. In fact, the transition temperature range of the suture could extend below the transition temperature range of the retainer. However, it is believed that it may be preferred to have the transition temperature range for the suture above at least a portion of the transition temperature range of the retainer.

**[0506]** Although one specific preferred embodiment of the applicator assembly 640 has been illustrated in Figs. 49 – 51, it is contemplated that the applicator assembly could have a different construction and/or mode of operation. For example, the applicator assembly 640 may have any one of the constructions and mode of operations disclosed in U.S. Patent No. 6,585,750, the contents of which are incorporated herein by reference.

**[0507]** The leading end portion of the force transmitting member 1172 (Fig. 51) extends part way around the end surface 1194 on the energy transmission member 1170. This results in the formation of a shield 1200 which extends part way around the retainer when the retainer is clamped between the flange 1192 and the end surface 1194 on the energy transmission member 1170. The shield 1200 has an inner side surface 1202 which forms a portion of a cylinder. The side surface 1202 engages the periphery of the retainer to position the retainer relative to the energy transmission member 1170 in a direction transverse to a longitudinal central axis of the energy transmission member.

**[0508]** The shield 1200 is effective to at least partially block engagement of body tissue with the retainer as the retainer is positioned in a patient's body and as energy is transmitted to the retainer from the energy transmission member 1170. It is contemplated that the shield 1200 could be constructed in such a manner as to extend completely around the retainer. This would allow use of the applicator assembly 640 in a moist environment or in an aqueous environment in which the retainer is completely or almost completely submerged in liquid.

**[0509]** The force transmitting member 1172 has a flange 1192 which engages the retainer. However, it is contemplated that the flange 1192 could be eliminated and a circular end plate provided at the distal end of the force transmitting member 1172. The use of a plate would provide for a wider area of engagement of the force transmitting member 1172 with the retainer.

**[0510]** Referring to FIGS. 52 - 55, the ultrasonic energy application apparatus 640 has been provided with an elongated, tubular sleeve member 1204 defining a passage therethrough, wherein the sleeve member 1204 is slidable over the force transmitting member 1172. The sleeve member 1204 includes a proximal end and a distal end, wherein the proximal end includes

a channel 1206 for engaging a pin 1208 positioned on the force transmitting member 1172. The channel 1206 and pin 1208 cooperate to limit the range of motion of the sleeve member 1204 over the force transmitting member 1172. In a first position, the distal end of the sleeve member 1204 is positioned to provide access to the gap between the end surface 1194 on the energy transmission member 1170 and the flange 1192 connected with the force transmitting member 1172, for insertion and removal of the suture retainer. In a second position, the distal end of the sleeve member 1204 covers the gap between the end surface 1194 on the energy transmission member 1170 and the flange 1192 connected with the force transmitting member 1172 for the application of ultrasonic energy. The sleeve member 1204 acts to protect the suture and adjacent tissue from the ultrasonic energy by shielding them from the ultrasonic energy while in the second position.

**[0511]** The proximal end of the sleeve member 1204 further includes a collar member 1210 having at least one notch 1212 configured to receive the suture. The collar member 1210 maintains the tension on the suture. For example, in a method of use the sleeve member 1204 is manually slid into the first position, providing access to the gap between the end surface 1194 on the energy transmission member 1170 and the flange 1192 connected with the force transmitting member 1172. The suture 1214 is then positioned in relation to the suture retainer 1216 and the suture 1214 and the retainer 1216 are positioned in the gap between the end surface 1194 on the energy transmission member 1170 and the flange 1192 connected with the force transmitting member 1172, where the suture 1214 and retainer 1216 are disposed between the end surface 1194 and the flange 1192. The suture leads 1218 a position in the collar member notches 1212, tensioning the suture 1214. The trigger 1188 is released, such that the biasing spring 1178 is effected to urge the housing 1184 to the left (as viewed in Figs. 48 and 50). The force applied by the housing 1184 is transmitted through the force transmitting member 1172 and flange 1192 to the retainer 1216. The sleeve member 1204 is moved to the second position, wherein the distal end of the sleeve member 1204 covers the gap between the end surface 1194 on the energy transmission member 1170 and the flange 1192 connected with the force transmitting member 1172. In the second position, the sleeve member 1204 forces the suture 1214 away from the end surface 1194 of the energy transmission member 1170. The non-engaged portion of the suture

1214 is positioned along the outer surface of the sleeve member 1204 and engages the notch 1212 in the collar member 1210. The ultrasonic energy is provided to the end surface 1194 of the energy transmission member 1170, securing the retainer 1216 to the suture 1214.

**[0512]** To remove the coupled suture 1214 and suture retainer 1216, the sleeve member 1204 is moved to the first position, providing access to the gap between the end surface 1194 on the energy transmission member 1170 and the flange 1192 connected with the force transmitting member 1172. The trigger 1118 is positioned to move the housing 1184 to the right (as viewed in Figs. 48 and 50). The rightward movement of the housing 1184 separates the force transmitting member 1172 and flange 1192 to the retainer 1216. The suture 1214 and retainer 1216 are removed from the gap between the end surface 1194 on the energy transmission member 1170 and the flange 1192 connected with the force transmitting member 1172.

**[0513]** It is further contemplated that the sleeve member 1204 includes a bias member, wherein the bias member biases the sleeve member into the second position. The sleeve member 1204 is manually slid into the first position, providing access to the gap between the end surface 1194 on the energy transmission member 1170 and the flange 1192 connected with the force transmitting member 1172. The suture 1214 is then positioned in relation to the retainer 1216 and the suture 1214 and the retainer 1216 are positioned in the gap between the end surface 1194 on the energy transmission member 1170 and the flange 1192 connected with the force transmitting member 1172, where the suture 1214 and retainer 1216 are disposed between the end surface 1194 and the flange 1192. The sleeve member 1204 can be held in the first position, for example, by the pin 1208 engaging a locking notch in the channel 1206.

**[0514]** Alternatively, the sleeve member 1204 includes a bias member, wherein the bias member biases the sleeve member 1204 into the first position, providing access to the gap between the end surface 1194 on the energy transmission member 1170 and the flange 1192 connected with the force transmitting member 1172. The suture 1214 is then positioned in relation to the retainer 1216 and the suture 1214 and the retainer 1216 are positioned in the gap between the end surface 1194 on the energy transmission member 1170 and the flange 1192 connected with the force transmitting member 1172, where the suture 1214 and retainer 1216 are

disposed between the end surface 1194 and the flange 1192. The sleeve member 1204 is manually slid into the second position, wherein the distal end of the sleeve member 1204 covers the gap between the end surface 1194 on the energy transmission member 1170 and the flange 1192 connected with the force transmitting member 1172. The sleeve member 1204 can be held in the second position, for example, by the pin 1208 engaging a locking notch in the channel 1206.

[0515] In an embodiment, the ultrasonic energy application apparatus 640 includes a safety switch. The safety switch is operably connected to the sleeve member 1204 and the force transmitting member 1172, such that the safety switch can prevent the energy source 1196 from transmitting ultrasonic vibratory energy to the energy transmission member 1170 when the sleeve member 1204 is in the first position. For example, when the sleeve member 1204 is in the first position, the safety switch is actuated into an “OFF” position, preventing the energy source 1196 from supplying ultrasonic vibratory energy to the energy transmission member 1170. This places the ultrasonic energy application apparatus 640 in a “SAFE MODE.” When the sleeve member 1204 is moved into the second position, the safety switch is actuated into an “ON” position, allowing the energy source 1196 to transmit ultrasonic vibratory energy to the energy transmission member 1170. The actuation of the safety switch to the “ON” position does not initiate the transmission of energy to the energy transmission member 1170, but instead places the ultrasonic energy application apparatus 640 in an “ACTIVE MODE,” wherein the energy source 1196 is capable of transmitting energy to the energy transmission member 1170.

[0516] It will be appreciated by persons skilled in the art that the present invention is not limited to what has been particularly shown and described herein above. In addition, unless mention was made above to the contrary, it should be noted that all of the accompanying drawings are not to scale. A variety of modifications and variations are possible in light of the above teachings without departing from the scope and spirit of the invention, which is limited only by the following claims.